MASTER OF SCIENCE

The influence of diagnostic information format on orthodontic treatment planning a feasibility study

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Award date:
2013

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2013

University of Dundee

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A Feasibility Study

A Craig Dunbar

This thesis was submitted in part fulfilment of the requirements for the degree of MSc in Orthodontics of the Faculty of Medicine, University of Dundee.

June 2013

The Orthodontic Department

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Acknowledgements

I would like to thank Professor D Bearn and Dr G McIntyre for their constant help from the earliest discussions of developing this investigation, to the final advice regarding the write up.

I am very grateful to Professor P Mossey and Dr A Cord for their time in the gathering of data.

I am indebted to Mr K Wood for the use of his knowledge and use of his technology.

I express my gratitude to Ms P Rauchhaus for her help in the statistical analysis of the results.

Thanks go to the administrative and nursing staff of the Orthodontic Department for helping to organise the attendance of the patients and accepting the associated disruption.

In addition, I am grateful to the laboratory staff of the Orthodontic Department for accepting an increased workload for a period.

Finally, I would like to thank Mr A McBride and Miss M Padilla for their help in record construction.

Declaration

This thesis is the original work of the author

Unless stated, all references cited have been consulted by the author

Work, of which this thesis is a record, has been done by the author

This work has not been previously accepted for a higher degree

Abstract

Aims: The aims of this feasibility study were to assess intra-observer reproducibility of treatment plans when developed from clinical examination, hard copy records and digital records. Inter-observer reproducibility of treatment plans was also assessed when using hard copy and digital records.

The aim was also to assess subject satisfaction with the conventional consultation system and to identify any differences of opinion between urban and rural subjects in the use of digital records for new patient consultations.

Materials and Methods: Twenty-seven subjects attended orthodontic consultations where two of four observers assessed them clinically and developed a treatment plan. Also at this consultation, records were taken enabling the construction of hard copy and digital records. Subjects were also asked to complete a questionnaire regarding their satisfaction with the consultation and perceived benefits of teleorthodontics.

Following a one month wash out period all observers were asked to develop treatment plans for every subject using hard copy records, then repeated after a further month using digital records.

Results and Conclusions: Cohen's kappa coefficient was used to show intra-observer reproducibility for clinical vs hard copy, hard copy vs digital and clinical vs digital treatment plans. Observer 1 showed good levels of agreement (κ=0.686, 0.692, 0.633). Observer 2 showed good levels of agreement when comparing clinical with hard copy records and hard copy with digital records, but only fair levels of agreement when comparing clinical and digital records (κ=0.681, 0.637, 0.362). Observer 3 showed fair agreement when comparing clinical and hard copy records

and hard copy with digital records, but poor agreement between clinical and digital records(κ=0.317, 0.326, 0.153). Observer 4 showed moderate agreement for each comparison of diagnostic record format (κ=0.543, 0.498, 0.592).

Inter-observer agreement using hard copy records was moderate and using digital records was fair (κ=0.490, 0.377)

Two thirds of subjects were very satisfied with the conventional consultation. No subjects were unsatisfied. Two subjects were from remote and rural communities, both felt that teleorthodontics would make it easier for them to receive an orthodontic consultation, save them time and money and one thought it could save them inconvenience.

LITERATURE REVIEW

1.1 Introduction

This literature review will explore the challenges faced in providing health care to remote and rural communities in Scotland. Established uses of telemedicine and teledentistry will be summarised as well as a review of the development of teleorthodontics. In addition, the acceptability of using digital technology for carrying out orthodontic examinations and treatment plans compared to conventional methods will be assessed. Means of gauging patient satisfaction with conventional referrals and consultations will be explored as well as their opinions on the potential use of teleorthodontics.

1.1.1 Healthcare in Remote and Rural Scotland

The 1912 Dewar Report[1] stated 'the difficulty of procuring specialist treatment in certain forms of physical defects, such as defective teeth and eyes, is, in the remote parts, particularly acute.' This report was made to highlight the inadequate medical service provided to the Highlands and Islands of Scotland and resulted in the formation of the Highlands and Islands Medical Service.

Almost one hundred years following the publication of the report, the 2007 'Needs Assessment Report on Remote and Rural Dentistry' highlighted that the remote and rural areas of Scotland still remain at a disadvantage in terms of dental service provision.[2]

Scotland is a sparsely populated country with an average of 0.66 persons per hectare compared to the EU average of 1.1 persons.[2] The definition of 'Remote and rural' has been determined in a variety of ways. In 1984, Randall suggested this included areas with 'less than 100 people per square kilometre or less than one person per hectare'.[3]

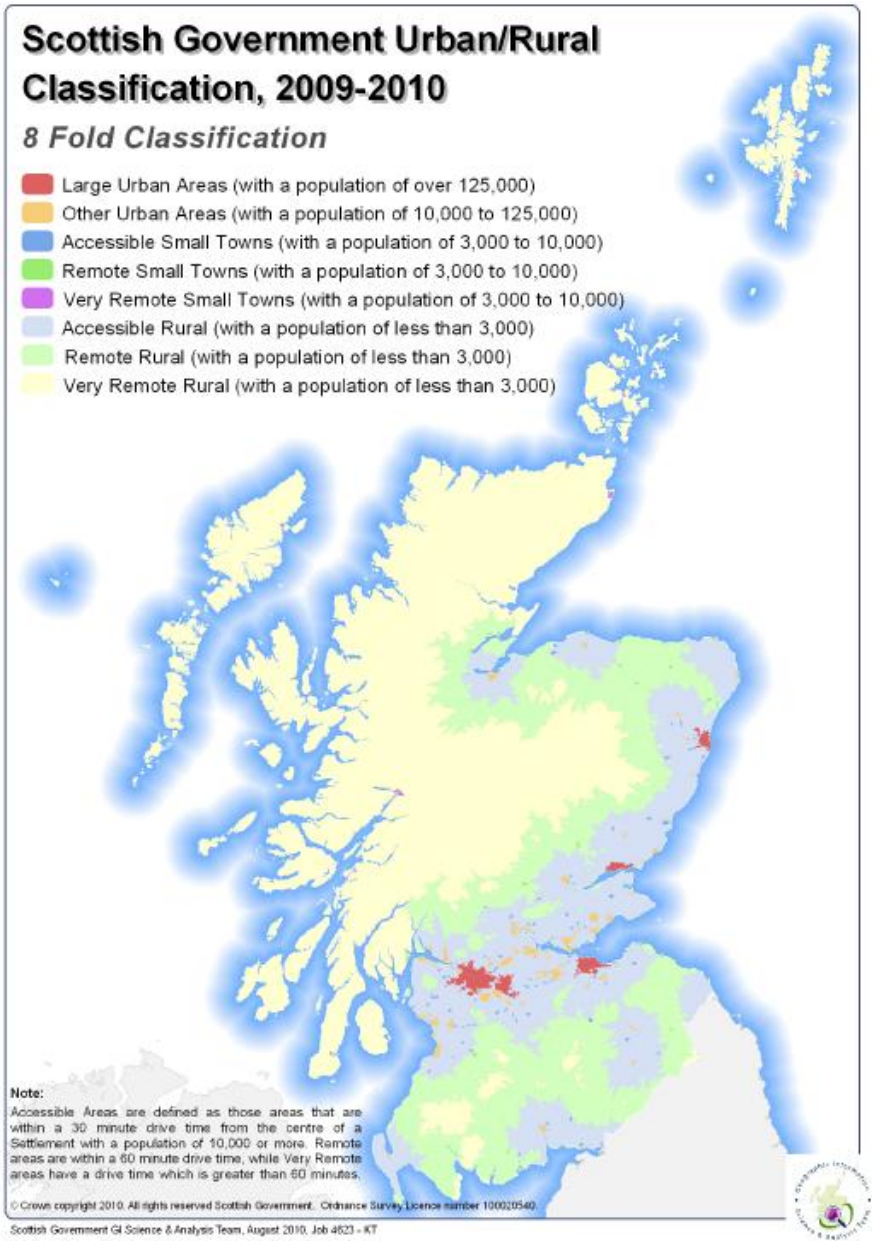
On this basis, 90% of Scotland would be classified as remote and rural despite the fact that less than 1/3 of the population would actually live in this area. The problem with this definition is the wide variability between areas that could be considered as remote and rural. Some communities with a reasonable population could be categorised in the same manner as an isolated croft.

Another method of defining a remote and rural area is the 'drive time' required to reach a major population centre.[3] Three per cent of Scotland's population live more than two hours from such a community. However, the problem with this definition is that it assumes universal car usage, so is of little relevance to those individuals to whom this does not apply, and where this is used for the planning of infrastructure and services, has the potential to increase social exclusion.

In 2004 the Scottish Executive defined rural Scotland as 'settlements of a population of less than 3000'.[4] Further defining features were stated relating to the accessibility of the settlements to more populated areas:

1. Accessible rural – those with a 30 minute or less drive time to the nearest settlement with a population greater than 10000
2. Remote rural – those with a greater than 30 minute drive time to the nearest settlement with a population greater than 10000

Figure 1 Population Classifications for Scotland



With this definition, nine health boards in Scotland are considered to be remote and rural, serving a significant population of 1.5 million people (Table 1).[2]

Table 1 Remote and Rural Health Boards in Scotland

Area health board unless stated otherwise	Population*
Scotland	5,094,800
Argyll and Bute Council area	90,870
Ayrshire and Arran	367,010
Borders	109,730
Dumfries and Galloway	148,340
Grampian	525,930
Highland	213,590
Orkney	19,590
Shetland	33,000
Western Isles	26,370
Rural total	**1,523,430**

*GROS mid-year population estimates 2005

1.1.2 Dentistry and Orthodontics

In terms of secondary care dentistry as a whole, there is little contemporaneous data available to illustrate provision of care in remote and rural areas of Scotland. Historical information implies that there are not enough hospital-based consultants providing services in remote and rural areas. Reduced recruitment and retention of secondary care dental service providers in these areas reduces access for the population and increases waiting times. Furthermore, the viability of services provided by single-handed consultants can be jeopardised when posts become vacant, particularly during periods of substantial cost-pressures within the National Health Service.

The reduced provision of orthodontic care to remote and rural areas was examined in the Needs Assessment Report on Remote and Rural Dentistry in 2007.[2] In this report, far fewer orthodontic appliance treatments per 100 courses of NHS treatment were provided within remote and rural health board areas compared to urban areas. An earlier study[5] found that some patients are required to travel around 40 miles from their general dental practitioner in order to access specialist orthodontic treatment compounding the problems with remoteness as discussed in Section 1.1.1. Coupled

with this, some individuals are required to travel a large distance to reach a sufficiently populated settlement that can support a GDP. Therefore, access to a specialist orthodontist can be extremely expensive and time consuming for patients.

The Scottish Executive and the succeeding Scottish Government has focused on ensuring that medical and dental care is provided to remote and rural communities, stating in 2000: 'Providing [care to] populations dispersed over many hundreds of miles of land and sea is one of the distinctive features of the NHS in Scotland'.[6] Further to this, the Needs Assessment Report on Remote and Rural Dentistry[2] made the following recommendations:

- Owing to the continued variable quality and comparability of information on NHS dentistry in Scotland, the progress of the recommendations set out in the Information and Technology Strategy for Dentistry in Scotland published in July 2001 should be reviewed and all outstanding recommendations implemented.
- The Scottish Executive Health Department (SEHD) should continue to support the development of innovative models of provision of dental services to meet local conditions.
- Further research and development of the use of tele-dentistry should be undertaken.
- Managed clinical networks for the dental specialties should be further developed to include rural areas of Scotland.

As stated, innovative and forward thinking methods of providing care for remote and rural populations are required to ensure efficient treatment is provided. In this context the use of tele-dentistry should be explored as it may provide solutions to the treatment of remote and rural patients that were not available before the advent of

digital technology. The use of digital technology is becoming more common in the general population and it is important that potential benefits be exploited. The North of Scotland Health Boards and NHS Education for Scotland set up a Managed Clinical Network and published a paper in 2009 setting out the principles of an e-orthodontics system.[7] This had four main aims:

1. Electronic triage of orthodontic referrals from primary care dentists
2. Provision of treatment plans and advice to primary care dentists from orthodontic consultants
3. Training and education allowing provision of continuing professional development
4. Electronic data interchange in primary care for payment of fees

This system is not yet operational due to problems with network support and infrastructure development. This is unfortunate as this type of system may result in more efficient use of NHS resources and a reduction in the burden of care for patients through travel subsidies, waiting times and service provision. Notably, O'Brien et al[8] found that 45% of orthodontic referrals were inappropriate. Therefore, if digital technology could be used to triage referrals it could mean that 45% of remote and rural patients would not have to attend an appointment that was potentially inappropriate. This in turn would save the NHS and patients' time and money and reduce waiting lists and waiting times.

1.2 Telemedicine

The simplest meaning of telemedicine is 'distant medicine' but there are a large number of definitions in different papers. A 2010 Cochrane review[9] provided a broad definition 'Telemedicine is the use of telecommunications for medical diagnosis and

patient care. It involves the use of telecommunications technology as a medium for the provision of medical services to sites that are at a distance from the provider. The concept encompasses everything from the use of standard telephone services through high speed, wide bandwidth transmission of digitized signals in conjunction with computers, fibre optics, satellites and other sophisticated peripheral equipment and software.' A narrower definition has been provided by Grigsby and Sanders[10] 'The use of telecommunications and information technology to provide health care services to persons at a distance from the provider.' All definitions include elements of information technology, distance between users and provision of healthcare.

The concept of telemedicine is far from new. As seen from a cover of a 1924 magazine,[11] the possibility of a doctor remotely examining a patient using audio-visual technology even pre-dates television (Figure 2).

Figure 2 Cover of Radio News Magazine 1924

Image courtesy of the Society for Computer Applications in Radiology

An example of an early form of telemedicine being implemented was medical advice provided to Scandinavian sailors, through radio transmissions whilst at sea in the 1920s. Technology has improved and its potential use has been explored by different health specialties, particularly dermatology, psychiatry, radiology, cardiology and accident and emergency. The potential in the use of educating medical professionals is also being explored.[12]

1.2.1 Types of Telemedicine

'Store and forward' is used by a referrer in a primary care facility gathering appropriate clinical information from a patient and then sending this onto a clinician in a distant secondary care facility. An example would be a remote and rural, primary care clinician sending a radiograph to a radiologist for further consultation. Advantages of the 'store and forward' method is that less sophisticated technology is required, it is therefore cheaper and the information can be viewed at a convenient time by the distant clinician.

'Real time' telemedicine allows instantaneous transmission from the patient to the distant clinician. An example of this use is monitoring of glycaemic control in type 1 diabetes patients, enabling nursing support as required. This allows immediate consultation, especially useful in emergency cases, however more advanced technology is required at greater expense.

In medicine, most clinicians view teleconsultations positively and feel they are likely to become an inevitable part of future practice. Lehoux et al[13] questioned clinicians in the medical fields of radiology, dermatology, pulmonary medicine, neurology,

cardiology and internal medicine on the matter. He found some clinicians had reservations and they insisted that the performance and user friendliness of the technology must be enhanced. The paper also found that clinicians in urban areas viewed telemedicine as advantageous for others in 'truly remote' hospitals and less so for themselves.

Clinicians in pulmonary medicine, neurology and cardiology expressed a need to view the patient face-to-face in order to carry out a full examination and produce subjective decisions. They were concerned about the reliance on information provided by a remote clinician to make diagnoses and plan treatment. In contrast, radiologists were more comfortable in receiving information from a clinician through telemedicine and providing a relevant answer. A further negative aspect voiced in the study was the amount of time required to provide a teleconsultation.

The 2010 Cochrane review 'Telemedicine versus face to face patient care: effects on professional practice and health care outcomes'[9] found a wide range of studies investigating telemedicine; therefore the review was limited to studies looking at patient care where the patient was distant from the clinician and 'at least two communication media used interactively.'

The literature search found more than 200 studies relevant to telemedicine; however, this was filtered down to only seven studies which met the inclusion criteria and were of adequate quality to be reviewed. The studies ranged over a host of potential uses of telemedicine such as rehabilitation following myocardial infarction, home monitoring of blood pressure and blood glucose.

All seven studies were randomised controlled trials and apparently well conducted, however no study reported a power calculation and small numbers of subjects was a common finding in all studies.

Due to the heterogeneity among the results gathered from a small number of studies, it was not possible to carry out an appropriate statistical analysis. The review stated that the seven studies did not show any detrimental effect on the care of patients with the use of telemedicine, however due to the small sample sizes, it cannot be concluded that there is no risk.

Telemedicine appears to be a feasible way to provide patient care, but there is as yet no evidence of clinical benefit which understandably needs to be explored further prior to major investment.

1.3 Teleorthodontics

The potential of telemedicine has been realised by some in the dental field. Nuttal et al[14] found inequality in the ability of general dental practitioners in rural areas to refer patients to a restorative secondary care provider compared to those in urban areas. Novel ways of referral were required, most notably teledentistry. A more recent feasibility study from Bradley et al[15] investigated the use of teledentistry for oral medicine referrals in Northern Ireland. This paper concluded that the inclusion of digital photographs with an appropriate referral could allow prioritisation of referrals and reduce waiting lists. In addition, the use of teledentistry was thought to have been particularly beneficial to elderly patients where appropriate information could be gathered through domiciliary visits, avoiding transporting the patient for a face-to-face consultation.

Conclusions from the feasibility study must be taken cautiously as only a small number of patients were included. In addition, there were no comparisons between provisional diagnoses made from the digital photographs and a face-to-face consultation. Therefore, the validity of the diagnoses made from the photographs was

unknown. The paper recommended further research into the cost-effectiveness of teledentistry and its use as a diagnostic tool.

There have been a limited number of studies assessing the use of this technology in orthodontics. Qualitative research has been carried out to assess the perceptions and attitudes of clinicians regarding the potential use of teleorthodontics. Palmer et al[16] surveyed orthodontists in Canada and found a generally positive feeling towards using computer technology to improve care. It was widely felt that the technology could improve communication between clinicians and patients, between clinicians in different specialties, increase practice efficiency, increase practice production, improve case diagnosis and treatment planning and increase patient satisfaction. However over half of the orthodontists surveyed felt that the costs associated with using the technology was a significant or insurmountable obstacle to teleorthodontics becoming widely used as well as increased time requirements and security of patient details.

On a similar theme Bradley et al[17] surveyed GDPs in a region of West Yorkshire, seeking their opinions on the potential use of an online orthodontic referral service. Results from this survey were slightly disappointing as only 46% of respondents stated that they would be interested in using teledentistry to receive orthodontic advice from a consultant. However, despite this paper being published in 2007, the questionnaire was distributed in 2003 when only 39% of respondents had access to the internet at home. Furthermore, only 8% had access to a digital camera. Those individuals who were keen on the use of teledentistry were also more likely to be familiar with digital photography, use removable appliances and already refer patients to orthodontic specialists and consultants. Due to the age of both of these papers, it is

hoped that many of the responders' perceived obstacles are now less of a concern as costs of the digital technology have reduced and they have become easier to use.

Stephens and Cook[18] published a paper reporting the attitudes of UK orthodontic consultants regarding the use of teledentistry to provide advice to general dental practitioners and their patients. From the responses received, they found that 70% of consultants agreed that further research should be carried out into this subject. Furthermore, 59% were interested in running an advisory service for the GDPs in their local area. The consultants raised some issues regarding the use of teleorthodontics: medico-legal aspects of advice, whether teleorthodontic advice counted towards hospital workload targets, quality of electronic records and the skills of GDPs to act on the advice that would be provided.

In the second of two papers regarding the use of teledentistry for screening new patient orthodontic referrals, Mandall et al[19] questioned GDPs' perceptions of this referral system in Greater Manchester and Derbyshire. The GDPs in this survey appeared to have been more positive towards the use of teledentistry than Bradley's[17] cohort as 71% thought that using teledentistry for orthodontic referrals was a 'good idea'. Three quarters of responders thought that teledentistry would improve communication between clinicians; however, they were not so sure that electronic referrals would be better than conventional referrals or shorten waiting lists. GDPs saw a major benefit in teledentistry for those patients from rural regions. Potential concerns expressed by GDPs about using teledentistry were expense of equipment, amount of clinical time required to produce referrals and current fee structure. They were also concerned about the security of the equipment in the surgery, but less so about the security and confidentiality of patient data.

The results from this study showed positive results among GDPs regarding willingness to use teledentistry, however the paper correctly stated that there may be response bias. This was because 34.5% of GDPs were unwilling to respond to the survey and may therefore have been critical of teledentistry, but this was not reflected in the results.

Studies have been carried out assessing clinical abilities of teleorthodontics for triaging referrals. Mandall et al[20] initially assessed the reliability of using only photographs to screen orthodontic referrals. Eight orthodontic consultants were asked to view intra- and extra-oral clinical photographs of 40 new patients and decide whether they thought the patients were appropriate for treatment. The consultants were then asked to assess the same photographs at least two weeks later and make a repeat judgment.

The results showed a wide range of intra-observer agreement regarding which patients required treatment with kappa scores ranging from 0.34-0.90. Inter-observer reliability was regarded as poor with a multiple-observer kappa score of only 0.37. These results were similar to previous studies looking at the reliability of orthodontists making clinical decisions as illustrated in table 2.

Table 2 Reproducibility of Clinical Decision

Author	Method	Clinical decision	Results
Ribarevski (1996)[21]	Full patient records (n=60) 10 Orthodontists	Extraction/non-extraction	Multiple-rater inter-examiner Kappa value =0.38 Agreement between combinations of two examiners within the group ranged from 0.11-0.73 Intra-examiner agreement kappa range =0.54-0.96
Lee (1999)[22]	Case vignettes (n=60) 10 Orthodontists	Diagnosis and treatment planning	Multiple-rater inter-examiner Kappa value =0.54 Intra-examiner agreement kappa range =0.24-0.90
Mandall (2001)[20]	Photographic records (n=40) 8 Orthodontists	Acceptance of Orthodontic referral	Multiple-rater inter-examiner Kappa value =0.37 Intra-examiner agreement kappa range =0.34-0.90

Mandall et al[23] also published a randomised controlled trial investigating the use of store and forward teledentistry in screening new patient referrals. This was a well carried out investigation with an appropriate sample size calculation, randomisation and use of a control group. For the teledentistry test group, information about the patient and malocclusion were sent by the GDP to the orthodontist as well as intra- and extra-oral digital photographs and photographs of any available radiographs. The orthodontist could then view this information via email and decide whether the patient was appropriate for treatment. This decision was then recorded.

These patients were also referred conventionally by the GDP in order that they could be assessed by the same orthodontist. The appropriateness of the referral was recorded again, allowing a comparison of the two decisions. In addition, there was also a control group of patients where only conventional referrals were carried out. When comparing the decisions made for appropriateness of teledentistry and conventional referrals, the results showed that teledentistry was a valid means of screening orthodontic referrals with a sensitivity score of 0.80. Specificity for the system was lower at 0.73. There was a risk, however that patients deemed not appropriate for treatment via a teledentistry referral would be deemed appropriate following a face-to-face consultation. In the study this was illustrated as 11 of the 22 patients who were not thought to have been referred appropriately via teledentistry were thought to have been referred appropriately following the face-to-face consultation.

The proportion of subjects that would have been accepted for treatment through teledentistry referrals were compared to the control group of conventional referrals. The proportion of inappropriate referrals for the teledentistry group was statistically significantly lower than the control group (0.037), indicating that using teledentistry to screen referrals would allow more appropriate referrals to be seen.

Using teledentistry to provide advice to GDPs has already been investigated. Cook et al[24] set up a teledentistry system so that GDPs could 'obtain advice about the need for and timing of orthodontic treatment; identify and receive advice for cases they could treat; identify cases that need referral for specialist care and explain to the patient and parent why such care is needed.' This system was set up using three levels. Level 1 was known as 'The Expert System' which consisted of a computer programme which allowed the GDP to carry out an orthodontic examination and provide a treatment plan for simple orthodontic treatment using removable appliances. If treatment was thought to be too complicated, it advised referral to a specialist.

The next level of the system was known as 'Whiteboarding'. This allowed the GDP to gather the information from the clinical examination and supplement it with digitised images of case records. This information could then be sent to an orthodontic consultant via the internet. The consultant could then assess the patient and provide advice regarding appropriateness and means of treatment to the GDP. This was an example of the store and forward method of teledentistry.

The third level was 'Dataconferencing'. This used real-time teledentistry to allow discussion of a case between the GDP and consultant where whiteboarding was insufficient. This live interaction allowed clarification of treatment plans and methods, but was more expensive to set up.

Following discussion with the dentists involved, the researchers found the GDPs were positive towards the teledentistry system and their patients viewed it as 'high tech'. The ability to seek immediate advice meant that patients could have orthodontic treatment started immediately, where appropriate, as opposed to being placed on a waiting list. The teledentistry advice system meant that there was a reduction in

inappropriately timed referrals and potential savings to the NHS were possible due to the reduced demands on hospital facilities.

The major negative aspect of using the system was the amount of time required to enter the clinical information into the software in order for advice to be provided. Due to this, the savings achieved in the hospital service may be offset by the increased costs incurred by the GDPs spending clinical time entering information. In addition, the system in this study did not appear to save many patients from inappropriate treatment as only one treatment plan was changed following advice from the orthodontic consultant. This study showed that GDPs viewed teledentistry as a useful tool, but cost effectiveness needed to be ensured for all parties.

A study by Berndt et al[25] went further than simply assessing the screening of patients with teledentistry and looked at its use in interceptive treatment. This case-control study compared improvements in PAR scores following interceptive orthodontic treatment for two groups of patients similar in gender distribution and overjet. One group was treated by orthodontic residents, supervised by on-site specialists with the second group treated by a non-orthodontist, supervised by a specialist using real-time teledentistry.

The results from the study showed that there was no statistically significant difference in the reduction of Peer Assessment Rating (PAR) scores between the groups following interceptive orthodontic treatment. Therefore, treatment carried out under real-time teledentistry supervision appeared to be an adequate method of improving a malocclusion. This may mean that teledentistry could enable interceptive orthodontics to be provided to patients via a GDP where access to specialist treatment would be extremely difficult due to distance or cost.

The results of this research were very encouraging; however, a number of elements could have been improved. Firstly, the two groups differed in ethnicity, age at start of treatment, Angle's classification and overbite. It may be that the only reason the teledentistry group's PAR scores improved to a similar extent to the direct supervision group was that they had less severe malocclusions initially. The means by which interceptive treatment was provided also differed with the directly supervised group using more headgear, functional appliance and serial extraction methods while the teledentistry group received more facemask, expander, holding arches, biteplane and intra-oral distaliser treatment.

There was more than three times the number of patients in the directly supervised group compared to the teledentistry group. It was thought that this was due to the greater convenience of acquiring pre- and post-interceptive treatment models for PAR scoring in the dental faculty as opposed to the non-orthodontic practice. Concerns regarding an under-powered study were confirmed with a post-hoc sample size calculation. Therefore, clinically significant differences in PAR score reductions between the two groups may not have been detected as statistically significant in this study.

Finally, there was no mention of cost requirements for the GDP in terms of the technology required to provide this service and the time provided by both the GDP and supervisor. Cost has been an important topic in most papers investigating teledentistry; however this was not mentioned in this report. Despite these failings, this study provides helpful information in how treatment, incorporating teledentistry could be quantified and compared.

There have been a small number of papers investigating the use of teleorthodontics spanning over a decade. Possible advantages in its use have been identified; however cost and time are major obstacles in the technology being used routinely. It is hoped that as the technology continues to develop at its current rapid rate, costs will reduce and the process will become faster and more user friendly.

1.4 Digital Technology

Lay people are becoming more familiar with digital technology and the potential of remote referrals is easily comprehendible. Studies have assessed digital orthodontic records and it is worthwhile considering the utility of this technology in teleorthodontics.

Traditionally orthodontic records have been hard copy photographs, radiographic films and plaster study models. Along with clinical examinations, these records have been used to diagnose malocclusion and plan treatment. Records are also used to monitor the progress of treatment and kept as an archive following the completion of treatment. The main negative aspects of conventional records are the costs required to produce them, the fragility of plaster study models, the inability to transfer them to other sites easily and the space requirement for archiving. One paper estimated that $17m^3$ of space is required to store study models in a unit which sees on average 1000 new patients per year.[26]

1.4.1 Digital Record Use in Cleft Lip and Palate

In the last 10-15 years digital photographs and radiographs have become far more common and their use in many orthodontic units have now superseded the conventional forms. This has meant that these records can be accessed readily by all

clinicians concerned with treating a patient even if there is a distance between the clinicians. This facilitates far easier communication.

Ali et al[27] investigated the use of digital photographic images of study models in determining the surgical outcomes for patients with unilateral cleft lip and palate. Initially, conventional plaster study models of patients having had surgical repair were scored using the modified Huddart/Bodenham system. Subsequently, 2 dimensional digital images were taken of these same models and once again the treatment outcome was scored using these images with the same system. When the scores were compared, good agreement was found when using the conventional study models or the two dimensional images. This is useful as it means audit and research of the surgical outcomes can be carried out in different centres without the need for plaster models being sent away. This means the images can be viewed by multiple individuals at once and risk of damage to the models is not a concern.

The use of digital study models in the evaluation of dental arch relationships of patients with unilateral cleft lip and palate was further investigated by Asquith and McIntyre.[28] Instead of using digital photographs of plaster study models, an R250 Orthodontic Study Model Scanner (3 Shape A/S, Copenhagen, Denmark) was used to create 3D digital study models. These models were then viewed on a personal computer allowing them to be manipulated, measured and stored.

Plaster study models of thirty 5 year-old patients with unilateral cleft lip and palate were scored using the 5 year-olds' and Modified Huddart Bodenham Indices by three specialist Orthodontists. At least one month later the same three Orthodontists scored the same models, but using the 3D digital format.

There were no statistically significant differences for the scores of the 5 year-olds' or the Modified Huddart Bodenham Indices when the 3D digital models were used compared to the plaster models.

The study concluded that the 3D digital models were a valid alternative to plaster models in evaluating dental arch relationships for patients with unilateral cleft lip and palate.

Leenarts et al[29] carried out a similar investigation comparing the scoring of study models of patients with cleft lip and palate with photographs of the models and also digital models derived from the plaster models. The paper concluded that the reproducibility of scoring for the plaster models, two dimensional photographic images and three dimensional digital models were comparable regardless of observer. Therefore, the digital formats could be used instead of the conventional models. One criticism of the photographs was that overjet and crossbites were not as easily assessed compared to the other formats. This may have been because the models could not be rotated with the photographs, but could with the other formats.

Table 3 Association of Cleft Lip/Palate Scoring between Plaster and Digital Study Models

Author	Method	Tests	Results
Ali (2006)[27]	Plaster vs digital photographs of study models (n=56) 4 examiners	Modified Huddart/Bodenham system scores OJ	Mean kappa value for modified Huddart/Bodenham system = 0.65 Mean kappa value for OJ = 0.68 Altman suggests this shows good agreement using digital photographs
Asquith and McIntyre (2010)[28]	Plaster vs R250 3D digital study models (n=30) 3 examiners	5-year olds index Modified Huddart/Bodenham index	No statistically significant difference between plaster and digital scores for 5-year old (p=0.12) or modified Huddart/Bodenham scores (p=0.506)
Leenarts (2012)[29]	Plaster vs photographs vs digital models (n=20) 4 examiners	Bilateral cleft lip and palate yardstick	Comparison between formats per observer weighted kappa scores = 0.692-0.885 Good to very good agreement according to Altman[73]

These papers show that study models in digital format are a valid alternative to plaster models in terms of scoring outcomes of surgery for patients with cleft lip and palate. This holds many advantages including ease of communication within managed clinical networks, reduced risk of damage to models, easier storage of records and improved availability for data gathering for research and audit.

1.4.2 Digital Study Models

The use of digital study models has not yet become routine, however as mentioned previously, the potential benefits with regards to the archiving and communication are beginning to be realised. Hajeer et al[30] described the potential uses of three dimensional imaging in orthodontics, particularly concentrating on constructing digital study models using OrthoCAD (Cadent, Fairview, NJ) technology. This involves alginate impressions of the dentition and bite registrations being sent to the company who digitise the models and send this back to the customer electronically. The customer can then view the models on their monitor in any direction and magnification. In addition, any view of the model can be saved, printed or sent to a colleague via secure email. Further software can then be used in order to help treatment plan the case using the digital models if desired.

Santoro et al[31] compared measurements made on conventional plaster models to those made on digital models using the OrthoCAD system. Measurements made of the plaster models were regarded as the gold standard. The results showed that the differences between measurements made from the plaster and digital models did not appear to be clinically relevant and they concluded that digital records can act as a clinically acceptable alternative to plaster models. Quimby et al[32] also compared

measurements, again concluding that digital models are a clinically acceptable alternative to conventional models.

Manufacture of digital models from alginate impressions appears to be clinically acceptable; however, some authors believe that inaccuracies occur due to shrinkage during the transportation phase to the company location. Some systems used in the production of customised Orthodontic appliances, such as Insignia (www.insigniasmile.com) and Incognito (www.hidden_braces.co.uk) try to limit distortion of models with the use of specific trays and poly vinyl siloxane impression material in an attempt to reduce inaccuracies as much as possible. Alternatively, the SureSmile system from OraMetrix (www.suresmile.com) gathers the arch information directly using a scanner. Mah and Sachdeva[33] explain that the system works by a scanner shining precisely patterned grids of light over the teeth and the distortion of the grid pattern is captured by a video camera in the handle of the scanner. Computer software then uses this information to build up a three dimensional image of the dentition in real time. Approximately 90 seconds is required to scan each arch.

Accuracy of laser scanning was assessed by Keating et al.[34] They compared measurements made between equivalent landmarks on three formats of models: plaster, digital and a reconstructed model from a digital scan. The results showed that there were no significant differences over time in the measurements for each format; therefore, there was good intra-rater reliability. When comparing linear measurements there were no significant differences between any format in the x and y planes, however all measurements in the z plane were significantly smaller for the reconstructed model compared to the plaster and digital models. This finding was supported by work carried out by Kusnoto and Evans.[35]

A recent study from Abizadeh et al[36] investigated the accuracy and reproducibility of digital models compared to their plaster originals using a large sample size of 112 models with a range of malocclusions.

The results showed that although intra-technique repeatability and inter-technique reproducibility were superior for the plaster models compared to digital models, these differences were unlikely to be clinically significant as the measurement differences were small. The authors found a systematic error in the scanning process as the digital model measurements were generally reduced compared to the plaster models. The scanning process did not produce a true one-to-one representation of the plaster model, however the source of this error was not due to alginate shrinkage as the digital models were made directly from plaster models. The authors thought that the cause of the systematic error might have arisen from discrepancies in the scanning process itself. In addition, the intra-technique repeatability was inferior for the digital models as the authors complained of difficulty in landmark identification using the 3D software.

The authors concluded that although digital models were not currently accurate enough to be used for scientific purposes, they were accurate enough to allow their use as an adjunct to clinical findings, allowing them to be used in treatment planning.

Stevens et al[37] assessed the validity, reliability and reproducibility of digital models compared to plaster models when taking measurements for the Bolton analysis and scoring the Peer Assessment Rating (PAR) index. No measurements carried out on digital models were found to be clinically significantly different from plaster models.

Digital models were a clinically acceptable alternative to plaster models, as these results did not show that an orthodontist would make a different diagnosis of a malocclusion with a digital model compared to a plaster model.

An alternative method of data gathering for study model construction was explored by Kau et al.[38] They investigated using cone-beam computed tomography (CBCT) as a means of taking radiographs as well as gathering data required in order for digital study models to be made using appropriate software. The authors supported the use of CBCT by pointing to advantages the technology has to offer: elimination of the need for impressions for models to be constructed, eliminating the need to send impressions away, rapid study model construction, increased data provided such as bone levels and root positions. They accepted that radiation dose for exposure of a CBCT was increased compared to that of standard orthodontic radiographs such as OPT, however it was much reduced to that of a multislice CT.

The results of the paper showed that there was no statistically significant difference in any of the measurements between the impression-based digital models and the CBCT models.

Similar work has been carried out by Tarazona et al.[39] They compared linear measurements from digital study models constructed from alginate impressions with models derived from CBCT scans of the same patients. The correlation of measurements between each model format was good and any differences were not thought to be of clinical significance.

Only two abstracts in English were found which described studies that compared the accuracy of plaster study models with digital study models produced from cone beam CT scanning of the original hard copy models. Hu et al[40] compared linear measurements from 10 lower arch plaster models with measurements taken from the digital models constructed using Simplant Pro 11.04 software (Materialise Dental, Leuven, Belgium). The results showed that measurements from the digital models

were underestimated compared to the plaster models, but no differences in measurement were significant.

Lv et al[41] also compared plaster study model measurements with 20 cone beam CT produced digital models from the plaster models. Again, measurements taken from digital models were reduced compared to plaster models and in this case crown widths, dental arch lengths and crowding were significantly different. However, despite these differences it was anticipated that they were clinically acceptable. Therefore, study models produced using cone beam CT are an acceptable alternative to plaster models for the purposes of treatment planning.

Table 4 Association of Measurements between Digital and Plaster Study Models

Author	Method	Tests	Results
Santoro (2003)[31]	Plaster vs OrthoCAD digital models (n=76)	Tooth width OB OJ	Digital tooth width and OB statistically significantly reduced ($p<0.05$, $p=0.0124$) No significant difference in OJ
Quimby (2004)[32]	Plaster vs OrthodCAD digital models (n=50)	Tooth width Arch length and width OJ and OB Space available/required	All measurements statistically significantly different ($p<0.0001$) apart from mandibular inter-canine width and mandibular space required
Keating (2008)[34]	Plaster vs Minolta VIVID 900 3D surface laser scanner digital models vs Stereolithography (n=30 plaster and digital n=1 stereolithography)	Linear measurements between landmarks	No statistically significant difference between plaster and digital measurements ($p>0.2$) No statistically significant differences between plaster ($p>0.3$) and digital ($p>0.5$) and stereolithograph model in x and y axes, but statistically significant difference in z axis ($p<0.001$)

Author	Method	Tests	Results
Abizadeh (2012)[36]	Plaster vs R250 digital scanner models (n=112)	Arch length Inter-molar and inter-canine width OJ and OB Centre line discrepancy Tooth height	Measurements from plaster models statistically significantly greater than digital in majority of cases. Differences no thought to be clinically significant
Stevens (2006)[37]	Plaster vs OrthoCAD digital models (n=24)	Linear measurements PAR Bolton analysis	No clinically significant difference in measurements
Kau (2010)[38]	Digital vs CBCT digital models (n=30)	Little's irregularity index OJ and OB	No statistically significant difference in any measurements
Tarazona (2013)[39]	Digital vs CBCT digital models (n=27)	Linear measurements	No clinically significant difference in measurements
Hu (2010)[40]	Plaster vs CBCT digital models (n=10)	Linear measurements	No clinically significant difference in measurements
Lv (2012)[41]	Plaster vs CBCT digital models (n=20)	Linear measurements	No clinically significant difference in measurements

This collection of papers has shown that although digital study models are not always statistically as accurate as the gold standard of plaster study models, clinically they are an acceptable alternative; therefore, treatment planning should still be possible using this information.

1.4.3 Stereophotogrammetry

Previously, the use of digital photographs of study models was described to facilitate communication between individuals in different locations for surgical treatment outcome analysis. The use of digital images of patients' faces are also important in the diagnosis and planning of treatment as well as monitoring differences in soft tissues as a result of growth or treatment. Standard digital photographs are commonly used in most orthodontic units although this method attempts to represent a three dimensional structure in two dimensions. 3D surface acquisition systems or stereophotogrammetry have been developed to gather a fuller image of the facial soft tissues. In simple terms, images are produced by a patient being positioned between at least two high-resolution digital cameras in natural head position. The cameras are connected directly to a computer and capture an image of the patient in 1.5 milliseconds, making the time period for movement of the patient and distortion of the image as short as possible. The captured images are then meshed together by the computer software to produce a three dimensional image of the patient's face which can be rotated, zoomed, saved as a universal readable file (*tsb) and sent to other clinicians via email. The use of two cameras produces an ear-to-ear image showing the full face. Currently the software has difficulty in processing areas where hair is present in the image, leaving dark areas in the reconstructed image. Therefore use of headbands has been

suggested to eliminate this problem, however little can be done to reduce the effect caused by facial hair.

The reproducibility and validity of stereophotogrammetry was investigated by Khambay et al.[42] In this study facial plaster casts of 12 patients were taken and 10 landmarks placed with their x, y and z positions recorded using a co-ordinate measuring machine (CMM). The investigators found low operator error and reproducibility error in the accuracy of locating landmarks using the stereophotogrammetry system compared to the CMM on facial plaster casts. System error was comparable to other 3D imaging systems. Therefore, it is implied that this stereophotogrammetry system appears to be a valid means of capturing a 3D image of a patient's face. The investigation by Khambay et al[42] was carried out in vitro.

Aynechi et al[43] alternatively carried out an investigation into the accuracy and precision of 3D anthropometric facial analysis in vivo. Generally, good agreement among the measurements was found between direct anthropometry and the 3D image. Some measurements from the 3D pictures were significantly different from the direct measurements and the proposed explanation was that the measurements were taken from bony landmarks or ones close to the ear. Inaccuracies associated with these landmarks are understandable, as bony landmarks cannot be palpated with 3D pictures so true soft tissue landmark positioning is difficult. In addition, shadow from the hair around the ears distorts 3D pictures making landmark placement and measurements difficult. Table 5 summarises other studies carried out to assess the precision and accuracy of stereophotogrammetry.

Table 5 Association between Conventional Measurements of the Face and Stereophotogrammetry

Author	Method	Tests	Results
Khambay (2007)[42]	Co-ordinate measuring machine (CMM) vs Di3D stereophotogrammetry (n=12 plaster casts of faces) 10 landmarks 2 observers	Accuracy of landmark location on full face plaster cast Reproducibility of landmark location on full face plaster cast over time	Accuracy – mean error compared to CMM = 0.2mm Reproducibility – mean error for Di3D = 0.13mm Clinically acceptable
Winder (2007)[44]	Vernier calliper vs Di3D stereophotogrammetry (n=1 mannequin) 18 landmarks 20 linear measurements	Accuracy of measurements from Di3D vs calliper Repeatability of landmark identification using Di3D over time	Accuracy - Mean difference between calliper and Di3D = 0.62mm Repeatability - Mean error 0.057mm

Author	Method	Tests	Results
Weinberg (2003)[45]	Digital callipers vs R250 3D camera (n=20 patients) 17 landmarks 19 measurements 2 observers	Accuracy of measurements for R250 vs callipers Precision of calliper and R250 techniques over time	7 of 19 R250 measurements showed statistically significant differences with calliper measurements ($p<0.003$) Greater precision with R250 technique than callipers
Gwilliam (2006)[46]	3dMD facial scanner (n=6 patients) 24 landmarks Intra-observer reproducibility = 1 observer Inter-observer reproducibility = 30 observers	Intra-observer reproducibility of landmarks over time Inter-observer reproducibility of landmarks	4 landmarks reproducible within S.D. <0.5mm 12 landmarks reproducible within S.D. <1.0mm 0 landmarks reproducible within S.D. <0.5mm 2 landmarks reproducible within S.D. <1.0mm

Author	Method	Tests	Results
Plooij (2009)[47]	3dMD stereophotogrammetry camera Images placed within reference frame (n=20 patients) 49 landmarks 2 observers	Intra-observer landmark identification error Inter-observer landmark identification error	Observer 1 located 2 landmarks with a statistically significant error ($p<0.05$) Observer 2 located 3 landmarks with a statistically significant error ($p<0.05$) 3 landmarks located showed a statistically significant error ($p<0.05$)
Aynechi (2011)[43]	Calliper vs 3dMD scanner (n=10 patients) 19 landmarks 18 measurements 1 observer	Accuracy of linear measurements for labelled and non-labelled 3dMD images with labelled calliper measurements Precision of measurements over time for each technique	Statistically significant difference for 7 3dMD labelled measurements Statistically significant difference for 6 3dMD non-labelled measurements No error clinically significant No technique showed systematic difference between measurements over time

Furthermore, Incrapera et al[48] highlighted that 3D surface acquisition systems are a good way of analysing soft tissue changes following orthognathic surgery. Their report provides more information regarding soft tissues than two-dimensional lateral cephalograms and there is no exposure to radiation for patients.

Despite the shortcomings of 3D imaging in terms of the lack of detail around ears and facial hair, the resultant errors are not thought to be clinically significant; therefore, stereophotogrammetry is thought to be a valid means of capturing the soft tissue image of a patient in three dimensions.

1.4.4 Digital Radiographs

Digital radiography has been becoming more commonly used in Orthodontics, particularly in dental hospitals. Digital orthopantomograms (OPGs) and lateral cephalograms can be produced by two methods. The system developed initially converts X-ray radiation to light. The light can then be converted to electrical charge by a charge-coupled device (CCD). The greater the electrical charge reaching the receptor, the darker the area on the radiographic image. This CCD system records the image immediately and can be viewed by the clinician on a computer screen without the need for processing.

The second system developed relies upon intensifying screens, incorporating photo-stimulable phosphor plates (PSP). The phosphor records X-ray energy hitting the plate and this information is stored on the PSP until it is scanned by a laser diode that excites the stored energy, which is released and converted into the image on the computer screen by CCDs. A processing stage is required for the PSP system; therefore, the clinician cannot view the image immediately.

Digital images consist of square pieces or picture elements (pixels) which are grouped together to produce the original image. The more pixels used to produce the image, the less distinct each pixel will appear when bordering one another, therefore the more pixels used to make a pixel matrix, the better the spatial resolution of the digital image. As opposed to an analogue radiographic image which can exhibit changes on a continuous gray scale, digital images must rely on binary information to represent the gray scale. A pixel on a digital radiographic image represents the intensity of X-ray radiation that hit the detector at that point. The binary number produced for each pixel is known as a 'bit' and the more 'bits' that are available for a pixel, the more gray scale values are available to represent the intensity hitting the detector at that precise spot. For example, a 6-bit image pixel has an option of 64 values in the gray scale. A value of 0 represents black where the detector shows X-rays have made unhampered contact to the film. A value of 63 represents a white area. An 8-bit image has 256 possible gray scale values; therefore, a more accurate representation X-ray intensity is possible in these pixels.

In summary, the quality of a digital image is dependent on the number of pixels and the number of gray scale values available.[49]

An advantage of digital radiography is the proposed reduction in radiation exposure to the patient by approximately 50% compared to conventional exposures. In addition, lateral cephalograms can be digitised on computer screen using appropriate software, thus removing the need to purchase digitising tablets. This software can also allow manipulation of the images' brightness and contrast allowing easier landmark identification. In addition, images stored on computer allow for easy retrieval and storage as well as multiple clinicians being able to view the image simultaneously if required, even if the clinicians are distant from one another.[50]

It is thought that image quality of digital radiographs is adequate compared to conventional radiographs and this has been investigated by various authors (Table 6).

In the study by Forsyth et al[51] 30 conventional cephalogram radiographs were captured and converted into digital images using a video camera. The study found that the pixel numbers available for the digital image was insufficient to represent the conventional radiograph adequately and the gray scale had inadequate range of values. Also, random errors and systematic errors were greater with the digital images. The use of a digital image representing the conventional radiograph fell short of adequate diagnostic quality in this study. However, the technology used to produce the digital image was not that which would be used currently. Neither CCD or PSP plates were used to create the digital images in this study; therefore, it was more of an assessment of the imaging technology than the production of the digital cephalograms. The authors state that for an improvement in the quality of the digital image, so that it is comparable to conventional counterparts, pixel number and gray scale values must increase. As the paper was originally submitted for publication in 1993 it is sage to assume that the technology available to display the image has become more advanced.

Geelen et al[52] incorporated the use of cephalometric images produced with PSP plates to test their reproducibility in landmark identification. Cephalometric images were displayed in a conventional modality, a digital hardcopy image and a digital image on a PC monitor.

From the results, it was found that the reproducibility of the landmarks was significantly different between the three modalities for 11 of the 21 landmarks, but no one modality allowed better reproducibility than another. It was noted however that

overall, the reproducibility of all landmarks was less for the image displayed on the monitor than the film and digital hardcopy modalities. This was not thought to be clinically significant.

This paper was published in 1998 and technological progress in the five years since the study by Forsyth et al[51] is likely to have contributed to the results. It would be anticipated that the further technological developments would make monitor displayed cephalograms comparable to conventional film images in terms of accuracy and reproducibility.

Chen et al[53,54] carried out a similar study to Geelen[52] whereby they wished to compare landmark identification and measurements carried out on conventional cephalograms with digital images of the same subjects.

The results of the comparison found that the location for each landmark on the digital image was statistically significantly different to the conventional image. Furthermore, the reliability of landmark identification on the digital image for points Po, Ar, ANS and UM was significantly reduced compared to the conventional image.

Chen et al[54] expanded on this initial study to assess the influence differences in landmark identification had on cephalometric measurements in conventional versus digital cephalograms using the same method and subjects. The comparison found that there was a statistically significant difference for all 27 measurements between the two image modalities. However, 21 of the 27 measurements were within one millimetre or degree which was not thought to be clinically significant.

Inter-observer errors between the two modalities were found to be significant in seven of the 27 measurements. This result was actually found to be quite encouraging as the previous paper had found that inter-observer error had been significant when identifying Po, Ar, ANS and UM. These four landmarks were then in turn used in 19

measurements, therefore the fact that only seven measurements showed a statistically significant inter-observer error suggested that discrepancies in the digital image compared to the conventional image would have less of an impact than anticipated. The authors concluded that this study supported the use of digital cephalograms as a reliable alternative to conventional images.

Bruntz et al[55] also wished to compare differences between conventional and digital cephalograms. To do this they compared three different modalities of pre-treatment and post-treatment lateral cephalograms.

The first modality was a conventional radiograph. The second was created by scanning radiographs from modality 1 into a digital format and made available on a computer monitor. The third modality was then, in turn produced by printing out the images from modality 2 at a 1:1 ratio using a laser jet printer.

The results showed that there was a distortion of the images when scanning them into digital format then printing this out. However, distortion was not thought to be clinically significant.

Some cephalometric measurements were significantly different between the digital computerised and printed modalities compared to the conventional image. But all significantly different measurements included points Po and Or. Po was previously shown to be unreliably identified by Chen et al.[53]

The study concluded that despite some distortion in the scanning phase, digital cephalograms could be used as a clinically acceptable alternative to conventional radiographs, allowing the benefits of digital technology to be exploited.

Table 6 Association of Measurements between Conventional and Digital Lateral Cephalograms

Author	Method	Tests	Results
Forsyth (1996)[51]	Conventional vs digital cephalometric radiographs produced by conventional radiograph placed on light box and captured using Pulnix TM760 video camera Digitisation using GTCO digipad 5A (n=30) 1 observer 26 landmarks, 24 measurements	Validity of measurements form digital vs conventional images (Random error) Comparison of reproducibility of replicate measurements between digital and conventional images (Systematic error)	Greater random error for digital compared to conventional image in 17 of 22 measurements. 5 errors statistically significant ($p<0.05$) Statistically significant systematic error in 18 of 22 measurements between digital and conventional images Differences clinically significant

Author	Method	Tests	Results
Geelen (1998)[52]	Conventional (i) vs PSP digital image printed by laser printer(ii) vs PSP digital image displayed on PC monitor(iii) (i+ii) digitised on tablet (iii) digitised with landmark sampling software (n=19) 6 observers, 21 landmarks	Inter-modality reproducibility of mean landmark locations for 6 observers Inter-observer reproducibility of mean landmark locations	11 of 21 landmarks showed statistically significant difference between modalities ($p<0.05$) 16 of 21 landmarks showed statistically significant differences between observers ($p<0.05$) Overall lowest reproducibility of monitor displayed image Differences of little clinical significance
Chen (2000, 2004)[53,54]	Conventional (i) vs digital image produced from scanning conventional image using VXR-12 scanner(ii) (i) Landmarks identified on transparent film, scanned then digitised (ii) Landmarks identified on computer monitor (n=10) 7 observers 19 landmarks, 27 measurements	Landmark location difference between (i) and (ii) Inter-observer landmark location error comparison between (i) and (ii) Linear and angular measurement differences between (i) and (ii) Inter-observer measurement error between (i) and (ii)	All 19 landmark locations statistically significantly different between (i) and (ii) ($p<0.05$) 16 of 19 landmarks showed greater inter-observer error on digital format. Only 4 landmarks were statistically significantly different ($p<0.05$): Po, Ar, ANS, UM All 27 measurements showed statistically significant difference between (i) and (ii) ($p<0.05$) 7 of 27 measurements statistically significantly different ($p<0.05$) Error clinically acceptable

Author	Method	Tests	Results
Bruntz (2006)[55]	Conventional (i) vs Digital produced by scanning conventional radiograph with Expression 1600 scanner(ii) Hard copy print outs of (ii) produced at 1:1 scale using LaserJet 4100N printer(iii) (i) Hand traced using acetate tracing paper (ii) Traced on screen with Dolphin Imaging 9 software (iii) Hand traced (n= 30 initial and 30 final radiographs for (i+ii)) (n=30 initial radiographs for (iii)) 1 observer 23 linear and angular measurements	Intra-modality comparison of measurement errors	(i) vs (ii) showed 6 measurements statistically significantly different($p<0.02$) (ii) vs (iii) showed 4 measurements statistically significantly different($p<0.02$) (i) vs (iii) showed 0 measurements statistically significantly different All statistically significantly different measurements included landmarks Or and Po Digital and hard copy cephs shown to be clinically acceptable

This series of reports show that chronologically the use of digital radiograph technology has become more commonly used and more accurate. The authors conclude that using digital cephalometry is now clinically acceptable; indeed, it is now commonplace in many orthodontic clinics. It is anticipated that as accuracy and reproducibility continues to improve, digital cephalograms will meet the gold standard.

1.4.5 The 'Virtual Patient'

With continued advancements being made in 3D image acquisition, some researchers have been investigating ways to integrate the available records in order to construct a 'virtual patient.' This would consist of a three dimensional image of the patient incorporating digital study models accurately positioned within the face of the patient, gathered via stereophotogrammetry. Rangel et al[56] and Rosati et al[57] have both investigated carrying this out and were able to produce reliable reproductions of a patient's dento-facial relationship. It is proposed that this can allow the monitoring of changes to the dento-alveolar and soft tissues following orthodontic and orthognathic treatment in three dimensions without exposure to radiographs. Nakasima et al[58] explored an alternative method of constructing a 3D model of a patient's head without the use of computed tomography. A reference skeletal/facial model created for the population in question, derived from 3D-CT scans from a group of volunteers was integrated with each subject's skeletal and facial models, constructed from cephalograms and stereophotogrammetry. The subject's 3D digital study model was inserted into their integrated skeletal/facial model. This resulted in a three dimensional representation of a patient's head without the need to expose them to a CT scan. Unfortunately, the reference skeletal/facial model for the population was

based on 3D-CT scans of only 21 volunteers. The reference model was unlikely to truly represent the mean for the entire population.

Kau et al[59] investigated the use of cone beam CT as the major method of gathering diagnostic records. They accept the increased dose of radiation associated with the exposure to CBCT compared to standard radiographs, however the exposure was only approximately 20% of that of standard CTs and the images were very accurate, quoting a nearly exact "1:1 image-to-reality" ratio. Coupled with stereophotogrammetry, an accurate soft and hard tissue representation of the patient could be constructed. Furthermore, CBCT could be used to construct 3D digital models which could be placed accurately within the three dimensional representation of the patient's head. The authors predicted that in the near future all diagnostic records will be able to be gathered from a single CBCT scan.

With the advent of digital technology and 3D imaging it is likely that conventional orthodontic records will be phased out. This will allow more accurate records to be gathered which are more easily stored, less fragile and are more easily distributed allowing better communication between colleagues and between patients and clinicians. As this technology becomes more common, it will reduce barriers for the use of teleorthodontics and allow improvement in the care of orthodontic patients in remote and rural areas.

1.5 Treatment Planning

For teleorthodontics to be a valuable tool in provision of care to patients in remote and rural areas, it should have a greater role than simply a screening mechanism for referrals. The digital technology available for distributing diagnostic records is

becoming more sophisticated, however it should be questioned whether these records are adequate for treatment planning of cases. Indeed, the most important question to be answered is how much information is required for a clinician to draw up a treatment plan that is equivalent to that devised when all diagnostic information is available or when the patient is available for an examination.

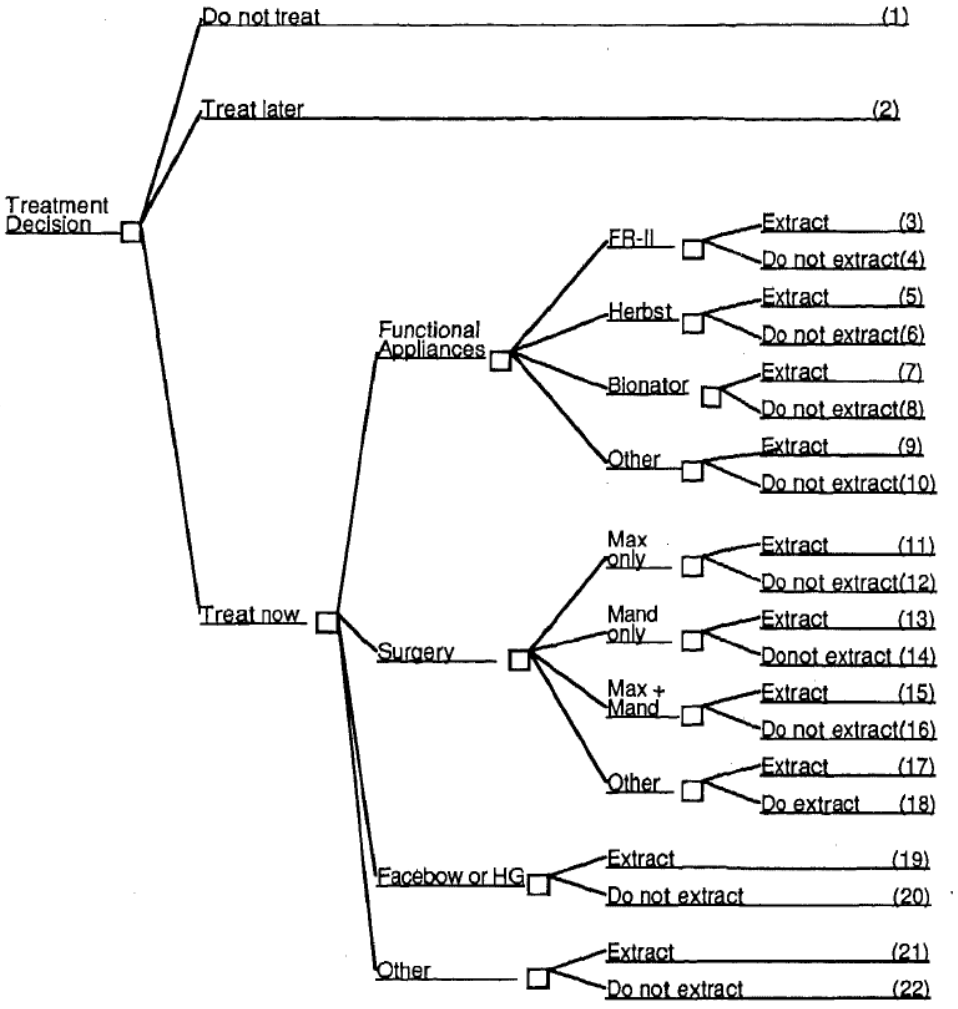
This was studied by Han et al[60] who investigated how relatively useful routine conventional diagnostic records were for treatment planning by orthodontists. They assessed how much diagnostic value was provided by different types of records. The diagnostic value or 'utility' of each record was based on the probability that the diagnosis, treatment process or treatment outcome would be influenced by the diagnostic procedure being carried out or not. The difficult aspect of testing a diagnostic procedure's 'utility' is: what is the gold standard the resultant treatment plan should be judged against?

In this paper the gold or diagnostic standard, as described by Han, is the treatment plan decided upon by each contributing orthodontist, following assessment of all diagnostic records available for each individual case. In this study, five orthodontists produced treatment plans for a total of 57 class II division 1 cases. Five diagnostic and treatment planning sessions were scheduled one month apart for each orthodontist, for planning of every case with an incrementally increasing amount of diagnostic information available. The records available at each session were as follows: i.) study models only (S); ii.) S+facial photographs (F); iii.) S+F+panoramic radiograph (P); iv.) S+F+P+untraced lateral cephalograms (C); v.) S+F+P+C+tracing (T) used as the diagnostic standard.

Following each planning session, each consultant was asked to make a decision about the patient's treatment, using a decision tree. This had various treatment options

available as shown in Figure 3. This allowed a reasonably detailed illustration of each orthodontist's treatment plan, for each case, following each session. Therefore, the changes to treatment plan, due to the influence of the addition of diagnostic records could be assessed.

Figure 3. Treatment Plan Option Tree



The proportion of plans from sessions i, ii, iii and iv equivalent to the diagnostic standard were calculated. In addition, to assess the consistency of the orthodontists' decision making, they were asked to plan 15 cases again with all diagnostic

information available. The proportion of agreement between the two sessions was analysed.

The results showed that in the majority of cases (55%), the provision of study models alone allowed as consistent treatment plans to be developed as the diagnostic standard. However as more diagnostic material was provided, treatment planning consistency with the diagnostic standard did not markedly increase. The proportion of agreement with each treatment session was as follows: i.) S=54.9%; ii.) S+F=54.2%; iii.) S+F+P=60.9%; iv.) S+F+P+C=59.9%. An analysis of variance indicated that the differences in proportion of agreement were not statistically significantly different among the variations in diagnostic records that were provided. Therefore, regardless of the amount of information used, treatment planning was unlikely to change significantly from the plan developed from the study models alone.

The results showed that the proportion of agreement between session iv.) to the diagnostic standard was 60%. This would suggest that the addition of a traced lateral cephalogram had a major effect on treatment planning. To investigate this, the authors analysed the agreement in planning following each session, using the decisions made from session iv.) as the diagnostic standard. They investigated whether there was statistically significantly more agreement in treatment plans when the traced lateral cephalogram had been removed from the equation. The results illustrated a similar pattern of agreement for sessions i.), ii.) and iii.) with iv.) as the diagnostic standard as the original results. Study models resulted in 54% agreement with maximum agreement of 61%

The question is then asked: what is the source of this inconsistency in treatment planning decisions? The paper shows that it is due to the lack of consistent decision making from the orthodontists themselves. Intra-observer reliability was only 65%

when analysing the 15 treatment plans made with all diagnostic information available on two separate occasions. This not only suggested that the one month 'wash out' period between treatment planning sessions was effective, but also, regardless of the amount of diagnostic records available, treatment planning consistency was likely to be quite low.

The paper suggested that the provision of study models alone was adequate for treatment planning and the incremental addition of diagnostic information made no significant difference. However, the question must be asked whether provision of study models was the most important factor to allow consistent treatment planning, or whether it was simply because the study models were the first diagnostic records provided? For example, would a similar proportion of treatment plans agree with the diagnostic standard if photographs or OPTs had been supplied instead of study models? Furthermore, do observers make an initial judgement on a treatment plan for a patient using the initial piece of diagnostic information, and then simply use further records to justify their original plan? Unfortunately this paper did not discuss this subject, but did underline the need for more information than simply diagnostic records in order to fully treatment plan a case, most notably gaining a history from a patient and carrying out a clinical examination.

Devereux et al[61] also investigated the influence provision of diagnostic records had on treatment planning, in particular lateral cephalogram radiographs.

Diagnostic information for six patients was taken, namely: 1.) summary of clinical findings; 2.) photographs of study models; 3.) standard intra- and extra-oral photographs; 4.) lateral cephalogram and panoramic radiographs; 5.) tracing of lateral cephalograms.

114 orthodontists completed the study and they were split into three groups. Each group had diagnostic information sent to them via a CD-rom on two separate occasions, at least eight weeks apart. On both occasions, the orthodontists were asked to treatment plan each of the six cases.

Group A received all diagnostic information apart from lateral cephalograms and tracings on both occasions. Group B received the same as Group A on the first round, but did receive lateral cephalograms and tracings for the second round. Group C received all diagnostic information in both rounds. This strategy allowed both intra-orthodontist and inter-orthodontist analysis of the influence of inclusion of the traced lateral cephalogram.

The results showed that overall; inclusion of a traced lateral cephalogram had no influence on treatment planning for five of the six cases. However, for one case, the inclusion of the traced lateral cephalogram influenced their treatment plan. The paper concluded that for the majority of cases, exposure to a lateral cephalogram was not required; however, it did have an influence in some cases, but exactly which cases was difficult to predict. It was interesting to assess the means by which the diagnostic data was distributed to orthodontists in this study. Mailing a CD-rom with digital records appears to be a form of teleorthodontics. The authors asked the orthodontists their opinion of using this method of planning. They had a number of criticisms including: 1.) inability to see patients' postured positions; 2.) no information regarding growth potential; 3.) inability to discuss treatment options with patients; 4.) no knowledge of patients' attitudes towards restorative or orthognathic treatment.

The paper further illustrated how orthodontists were unlikely to be influenced by the provision of an additional piece of diagnostic information when they were already

likely to have made their decision with the first few records. It was however interesting to note some of the criticisms of teleorthodontics.

As mentioned previously, digital diagnostic records are becoming more sophisticated. One example of this is 3 dimensional study models. These accurate representations of the dentition can be manipulated and viewed in a similar way to normal study models, but do not allow the same dextrous handling, which is important to orthodontists. Whetten et al[62] studied variations among orthodontic treatment plans for class II patients when 3D models were compared to plaster models. They assessed intra-observer agreement for need for surgery, extractions and auxiliary appliance use, dependent on study model format. Pre-treatment plaster study models, photographs, panoramic radiographs and lateral cephalograms of 10 patients were duplicated. They selected a group that would include two patients requiring 'almost surely surgery', two others requiring 'almost surely not surgery' and the remaining six requiring 'truly borderline' treatment. The patients' study models were digitised. Twenty orthodontists treatment planned the 10 cases using the pre-treatment records with digital study models as opposed to the plaster models. Their treatment plans were recorded using a decision tree modified from Han et al.[60]

At least one month later the same 20 orthodontists treatment planned the same 10 cases, but this time with plaster study models. The treatment plans from this round were the gold standard. A control group of 11 orthodontists carried out the same two treatment planning sessions, but using plaster study models on both occasions.

The results from the study showed that the use of digital study models did not significantly affect treatment planning decisions. The need for surgery, type of surgery and use of auxiliaries did not vary significantly regardless of whether the

cases were planned with plaster or digital study models (Table 7). Using plaster models tended to result in more extractions being planned than with digital models, however this was not a statistically significant difference.

Table 7 Cohen's kappa coefficient of Treatment Plans

Comparison	Plan	κ coefficient
Digital vs plaster	Surgery	0.549
	Extractions	0.570
	Auxiliary appliance	0.539
	Overall agreement range	0.777-0.870
Plaster vs plaster	Surgery	0.671
	Extractions	0.626
	Auxiliary appliance	0.672
	Overall agreement range	0.818-0.873

Rheude et al[63] carried out a very similar study to Whetten et al[62], comparing treatment planning decisions made with the use of digital study models against plaster models. The paper found that statistically significant differences in diagnostic findings between the digital and plaster models were not clinically significant. Another observation of the paper was that as orthodontists grew more accustomed to viewing digital models, less diagnostic variation was noted between plaster and digital models. Therefore, as the orthodontists became more accustomed to the technology, they were more likely to make consistent decisions. One criticism of this paper was that the diagnosis and treatment planning using plaster models took place only 30 minutes after using the digital models. Recall bias was a strong possibility in this study and may have influenced the results.

Digital study models are a valid alternative to plaster study models for treatment planning. This is encouraging for the prospects of teleorthodontics as although there may be differences in measurements between plaster and digital models, this does not appear to affect clinical decisions and treatment planning.

It is worthwhile reiterating that assessing consistency in treatment planning between orthodontists is fraught with difficulty, largely due to variations in decisions made between them. As noted in Table 2 Ribarevski et al[21] and Lee et al[22] found poor inter-clinician agreement for treatment planning decisions and even intra-clinician agreement was only described as moderate.

1.6 Patient Satisfaction

The National Health Service has been striving to provide improved patient care and in the NHS National Plan,[64] produced in 2000, the organisation promised that "for the first time patients will have a real say in the NHS." Key tools in applying this are the patients' survey and forum to make the care centred on the patient. In orthodontics, clinical governance has become an essential part in the provision of quality service to the patient. McNair et al[65] developed a questionnaire designed to assess orthodontic patient satisfaction following treatment.

The first step in this process involved the use of qualitative research methods to gain an insight into the views of adolescent patients regarding orthodontic treatment. Great emphasis was placed on focusing on the opinions of the adolescent patients as opposed to their parents. Initially the qualitative research was to be carried out on adolescent patients undergoing orthodontic treatment at a district general and dental hospital. The patients were asked to attend a focus group meeting to talk about their

experiences. The patients were not asked to attend with a parent, but with a fellow adolescent or 'buddy'. Unfortunately, patient uptake to attend these meetings was very poor, therefore the protocol was changed. Patients could also be recruited from specialist practices where focus groups were held immediately following the removal of an appliance and the patient was waiting for a retainer to be fitted. This allowed more convenience for the patient to attend the focus group and improve recruitment. In addition, telephone interviews were offered to patients as an alternative to attending a focus group.

Following focus group and telephone interview data gathering, the major issues regarding treatment were identified and analysed. Useful information was gathered regarding patients' views on perceived benefits of treatment, clinical surroundings, clinical factors associated with treatment, information provided, experience of wearing braces, appearance and self-confidence at the end of treatment.

In a subsequent paper McNair et al[66] detailed their efforts in developing the information provided from the qualitative research into a questionnaire. This was then tested for readability, reliability, validity and ease of administration.

The questionnaire was developed with the following sections:

A and B – Age, gender, type of appliance, length of treatment

C – Reasons for treatment

D – Visiting the orthodontist

E – Having treatment

F – Information on braces before treatment

G – Wearing a brace

H – Problems with wearing a brace

Test-retest reliability was assessed by asking a number of patients to complete a questionnaire with a researcher present at the clinic. After 12-14 weeks, the same questionnaires were sent to the same patients. They were asked to complete these questionnaires again and send them back to the researcher. All sections showed excellent to good reliability apart from two questions in section C which were surprisingly only associated with moderate reliability.

Readability was scored using the Flesch Reading Score and Flesch-Kincaid Grade Level Score. The questionnaire was suitable for a 10 year-old's reading ability.

Ease of administration was assessed by timing how long a sample of the patients took to complete the questionnaire. This ranged from 5 to 15 minutes with a median and mode of 7 minutes.

Validity was assessed using two tests. Construct Validity assessed the accuracy of statements written in the questionnaire compared to information that can be ascertained from clinical notes such as 'when did you start wearing braces?' The majority of agreement in this test was excellent. Criterion Validity compared responses from the questionnaire to those from a telephone interview carried out 6-8 weeks after the initial questionnaire was completed. Agreement was poor for half of the questions examined. Three possible reasons for this were identified: the questionnaire was not valid, methodological differences between the paper and telephone questionnaire or the telephone interview was not an adequate method of testing the validity. Unfortunately, no alternative methods with a gold standard measure were identified.

Despite the uncertainty regarding the criterion validity associated with this patient satisfaction questionnaire it has been published by the British Orthodontic Society (BOS) as a means for orthodontists to assess the quality of care they provide.[67]

Findings from the relevant sections of four audits of patient satisfaction published in the BOS Clinical Effective Bulletin are summarised in Table 8.

Table 8 Results of BOS Patient Satisfaction Questionnaires

Author	Results
Nasr (2009)[68]	2% of respondents dissatisfied due to a lack of information provided about treatment. 47% of respondents dissatisfied with ability to make appointments.
Balakrishnan (2005)[69]	93% of patients satisfied that orthodontist explained treatment adequately. Orthodontist was friendly and provided enough information in 96% and 94% of responses respectively. 76% of responders could arrange an appointment when it suited them. 60% found it easy to contact the orthodontist to make an appointment.
Lo and Yap(2005)[70]	72% of patients received information leaflets before the treatment. 74% satisfied with information provided to them at each visit. 76% felt able to discuss treatment with orthodontist at each visit
Seed (2007)[71]	100% of patients received information about orthodontic treatment before brace fitted. 97% felt information prepared them adequately for treatment

It is interesting to note that the BOS patient satisfaction questionnaire, so commonly used in audits throughout the country, has not been proven valid. There is doubt as to the responses provided by patients in the clinic are equivalent to those given at home a number of weeks after data was gathered from the first questionnaire. Furthermore, the initial questionnaire was intended to gauge the opinions of patients following the completion of treatment. It may be more relevant to assess patient satisfaction whilst treatment is ongoing. However, no other questionnaires in orthodontics have had such a degree of preparation and in terms of readability, reliability and access it is adequate.

To date there has been no questionnaire developed to assess patient satisfaction in relation to the orthodontic referral process, and this would be relevant to this pilot study. Therefore, relevant sections of the BOS patient satisfaction survey have been incorporated into the questionnaire developed to assess patients' views on conventional and digital referrals.

1.7 Summary

There is a lack of literature on the subject of teleorthodontics and a continuing need for a novel way of providing orthodontic care to patients living in remote and rural areas of Scotland that is convenient and cost-effective.

Branches of medicine have been exploring the potential uses of telemedicine for some time, with certain disciplines more comfortable with its use than others. The papers that have been published on teleorthodontics give an impression of a generally positive attitude towards its use from GDPs, orthodontists and patients. Although cost-effectiveness is quite correctly a subject regularly raised, little research has been carried out to assess this. Some studies have also implied positive findings for using

teleorthodontics in supplying advice and allowing interceptive treatment to be carried out, but there has been no research into treatment planning via teleorthodontics.

There has been research carried out looking at the technology available to gather digital records that could be transferred easily between locations facilitating teleorthodontics. Generally, digital records appear to be clinically acceptable alternatives to conventional records. Indeed it is anticipated these will become commonplace in orthodontics allowing construction of a 'virtual patient' with the amalgamation of data from different records.

The amount of information required to treatment plan a case suggests that in general, where all the teeth are erupted, the majority of cases can be planned using study models alone.[60] Using digital study models for treatment planning also appears to be valid; however research into treatment planning regularly states the importance of the clinical examination, although this is rarely investigated.

AIMS AND NULL HYPOTHESES

2.1 Aims

1. To assess intra-observer reproducibility of treatment planning when comparing the use of different diagnostic information formats, namely: clinical examination; hard copy diagnostic records; digital diagnostic records.
2. To compare inter-observer reproducibility of treatment planning when comparing the use of different diagnostic information formats: hard copy diagnostic records; digital diagnostic records.
3. To assess subject and parent/guardian satisfaction with the conventional consultation system.
4. To identify any differences of opinion between subjects from urban and rural communities in the use of digital records for new patient consultation.

2.2 Null Hypotheses

1. There are no differences in intra-observer treatment planning decisions or inter-observer treatment planning decisions, following initial clinical examination, use of hard-copy diagnostic records or use of digital diagnostic records.
2. There is no difference in subject and parent/guardian satisfaction with the conventional consultation system between rural and urban patients.
3. There is no difference in perceived benefits in the use of digital diagnostic records for remote referrals between urban and rural patients.

MATERIALS AND METHOD

3.1 Study Design

This prospective observational cross-sectional feasibility study was designed to assess the influence that differences in consultation methods have on orthodontic treatment planning by consultants. Consultants drew up a treatment plan for each member of a group of subjects, using three different methods of consultation. The subjects were referred for new patient consultations to the Orthodontic Department at Dundee Dental Hospital.

Ethical approval was obtained from the East of Scotland Ethics Service Research and Ethics Committee.

3.2 Participants

The participants in the study were four consultants in the Orthodontic Department at Dundee Dental Hospital.

3.3 Subjects

3.3.1 Sample size

Prior to commencing the study, work was carried out in order to calculate an appropriate sample size. The initial aim was to recruit the appropriate number of subjects in order to determine if a change in the method of consultation would result in clinically significant changes to treatment plans. In order to do this the following email was sent to the specialist orthodontists within the Tayside Orthodontic Managed Clinical Network:

‘A survey of UK Orthodontic consultants in 1996 showed that the following

percentage of patients received the different types of treatment:

- Growth modification - 12%
- Orthodontic treatment only - 81%
- Surgery - 7%

The question I ask is: what changes to the above percentages would be clinically important? For example, would an increase in surgery treatment plans of 5% to 12% be clinically important in your view? What about a change by 1% to 8%, would that be clinically important?'

From the replies, the results were discussed with a statistician at the Tayside Clinical Trials Unit (TCTU). It was felt that inadequate resources were available to establish if a change in the orthodontic record format would have a significant effect on treatment planning. Due to the variance among the replies, the sample size would be too large. It was therefore decided that a feasibility study involving 25-30 subjects would provide valuable information on differences in treatment planning, patient perception of teleorthodontics, enable a sample size estimation and aid in future study design.

3.3.2 Inclusion/Exclusion Criteria

Potential subjects were drawn from consecutive new patients referred into the Orthodontic Department by Specialist Practitioners, General Dental Practitioners, General Medical Practitioners and other departments within Dundee Dental Hospital.

Inclusion criteria: Participants were included in the study if they had been referred to the Orthodontic Department of Dundee Dental Hospital for an orthodontic assessment and/or treatment.

Exclusion Criteria - Participants were excluded if they had previously undergone orthodontic treatment, had no original referral in their clinical notes, a cleft lip/palate

or other congenital craniofacial anomaly was present, if aged under 12 years and/or in the mixed dentition. In addition, if subjects and their parents/guardians were unable to understand written and verbal explanations of the study adequately to provide informed consent, they were excluded.

3.3.3 Patient Information Sheets

Prior to attending their first appointment in the Orthodontic Department, potential subjects were sent patient information sheets (PIS). These informed the potential subjects of the purpose of the study, what would be required if they took part, time requirements and exclusion criteria. The PIS outlined contact details for complaints and assured the subjects that they could leave the study whenever they wished and that all information gathered would remain confidential. In addition, this provided contact information for the investigators in case the potential subjects had any further questions regarding the study in advance of their appointment.

Three different versions of the PIS were sent out to the potential subjects dependent on their age. Versions were produced for 12 to 15 year olds (Appendix 1), 16 to 18 year olds (Appendix 2) and over 18s (Appendix 3) with appropriate language used to explain the study in each as accepted by the East of Scotland Ethics Service. A copy of the over 18s PIS was sent with the 12 to 15 year old version for the potential subjects' parents/guardians to read and discuss with their child.

3.4 Materials

After gaining consent, orthodontic records (impressions for study models, clinical photographs, radiographs and stereophotogrammetry 3D scans) were obtained for all

subjects. Hard-copy records were converted to an electronic format in order for treatment planning using digital records, to be carried out.

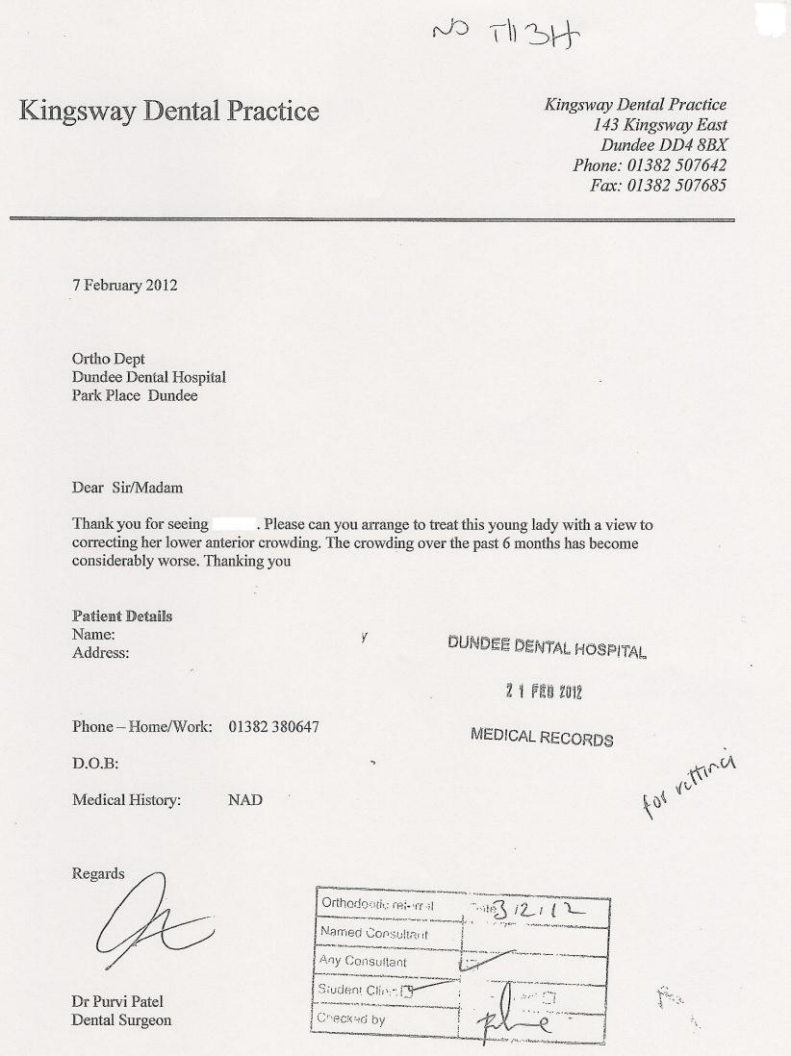
3.4.1 Referrals

Although not strictly records, referrals are an important piece of information in order for a suitable treatment plan to be drawn up. They can provide details of presenting complaints, attitudes towards treatment, past dental and medical health and details of any previous orthodontic treatment.

When the subjects attended their initial appointment, their referrals were available in their clinical notes. These were photocopied using a Ricoh Aticio MP C4501 (Ricoh, Tokyo, Japan) photocopier and anonymised by obscuring all identifiable details using opaque self-adhesive white labels on a photocopy of the referral.

The anonymised referrals (Fig. 4) were then scanned using a Hewlett Packard C4680 scanner (HP, Palo Alto, California, US) to produce electronic versions and stored on a password protected NHS computer network.

Figure 4 Digitised Orthodontic Referral



NO T113H

Kingsway Dental Practice

Kingsway Dental Practice
143 Kingsway East
Dundee DD4 8BX
Phone: 01382 507642
Fax: 01382 507685

7 February 2012

Ortho Dept
Dundee Dental Hospital
Park Place Dundee

Dear Sir/Madam

Thank you for seeing . Please can you arrange to treat this young lady with a view to correcting her lower anterior crowding. The crowding over the past 6 months has become considerably worse. Thanking you

Patient Details
Name:
Address:

DUNDEE DENTAL HOSPITAL
21 FEB 2012
MEDICAL RECORDS

Phone – Home/Work: 01382 380647

D.O.B:

Medical History: NAD

for retrieval

Regards

Dr Purvi Patel
Dental Surgeon

Orthodontic referral	31212
Named Consultant	
Any Consultant	
Student Clinic	
Checked by	

3.4.2 Intra-oral Photographs

Dundee Dental Hospital's medical photographer recorded intra-oral photographs of each subject using a Nikon D90 camera (Nikon, Tokyo, Japan) with a Sigma 105 DG Macro lens (Sigma, Welwyn Garden City, UK) and Sunpak 16R pro ring flash (Sunpak, Tokyo, Japan). The views taken were anterior teeth in occlusion, right lateral, left lateral, upper and lower occlusal views (Fig. 5).

Digital versions of the photographs were supplied on a CD-ROM having been converted to JPEG files using Microsoft Paint (Microsoft, Redmond, California, US). Anonymous, colour, paper copies were printed. The digital images were stored on a password protected NHS computer network.

Figure 5 Digitised Intra-Oral Photographs

3.4.3 Extra-oral Images

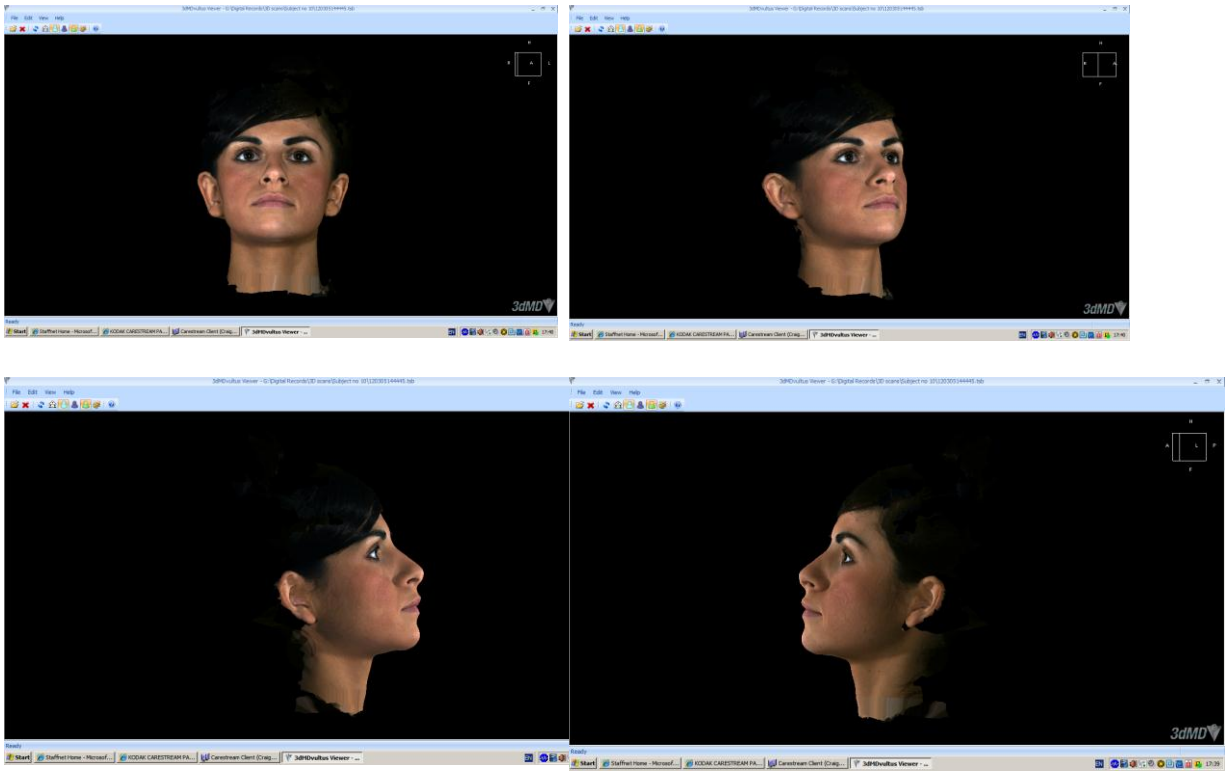
Extra-oral images were produced initially by taking 3D electronic stereophotogrammetry images of the subjects' faces. This was done using a 3dMD face System (3dMD, Atlanta, US). This required the subjects to position themselves

between two image capturing devices, each of which contained three digital cameras. The operator capturing the image ensured that the subject's inter-pupillary line was parallel to the floor and that their hair was kept away from their face. The subject had to remain still for only 1.5 milliseconds in order for the image to be captured. Within 20 seconds a 180° image of the subject's face, from ear to ear, could be viewed on a laptop using 3dMDvultus Software Platform (3dMD, Atlanta, US). The image could be rotated so that different views of the subject's face could be examined and saved in various formats. The saved images could then be viewed on any computer where 3dMDvultus Software Platform was installed.

The images of the subjects were saved onto a memory stick and transferred onto a password protected NHS computer network. All other copies of the images were deleted.

From the 3D digital images, 2D facial images were produced by rotating the images to produce front, right and left lateral and ¾ views of the subjects' faces. These images were saved as JPEGs using Microsoft Paint (Microsoft Corporation, Redmond, California, US) and anonymised. Colour prints were produced to act as standard extra-oral orthodontic records (Fig. 6).

Figure 6 Stereophotogrammetry Images



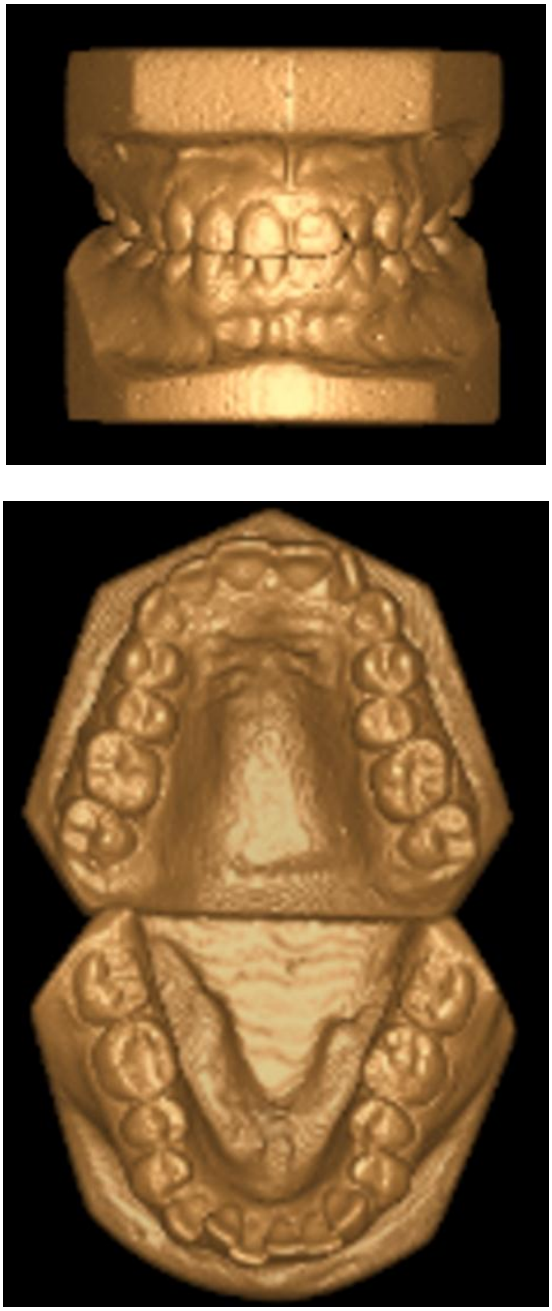
3.4.4 Trimmed Study Models

Plaster study models were poured up from alginate impressions of the subjects' upper and lower arches. They were then trimmed according to a wax bite taken clinically to represent the position of maximum intercuspation.

The conventional plaster study models were anonymised and identified only by subject numbers. They were subsequently scanned using a cone beam computed tomograph (CBCT) I-CAT Next Generation scanner (Imaging Sciences International, Hatfield, PA 19440) in the Dental and Maxillofacial Radiology Department at Dundee Dental Hospital. The scans were carried out at a definition of 0.2 voxels. These models were scanned with the teeth in maximum intercuspation and apart, allowing the subjects' teeth to be viewed in occlusion and each upper and lower arch to be viewed from the occlusal aspect meaning that crowding and spacing could be

assessed. The digital images were saved onto a password protected NHS computer network (Fig. 7).

Figure 7 Digital Study Models from CBCT Scan



3.4.5 Radiographs

Appropriate radiographs were taken of subjects on their initial appointment as required for a normal clinical assessment to be carried out. The radiographs taken

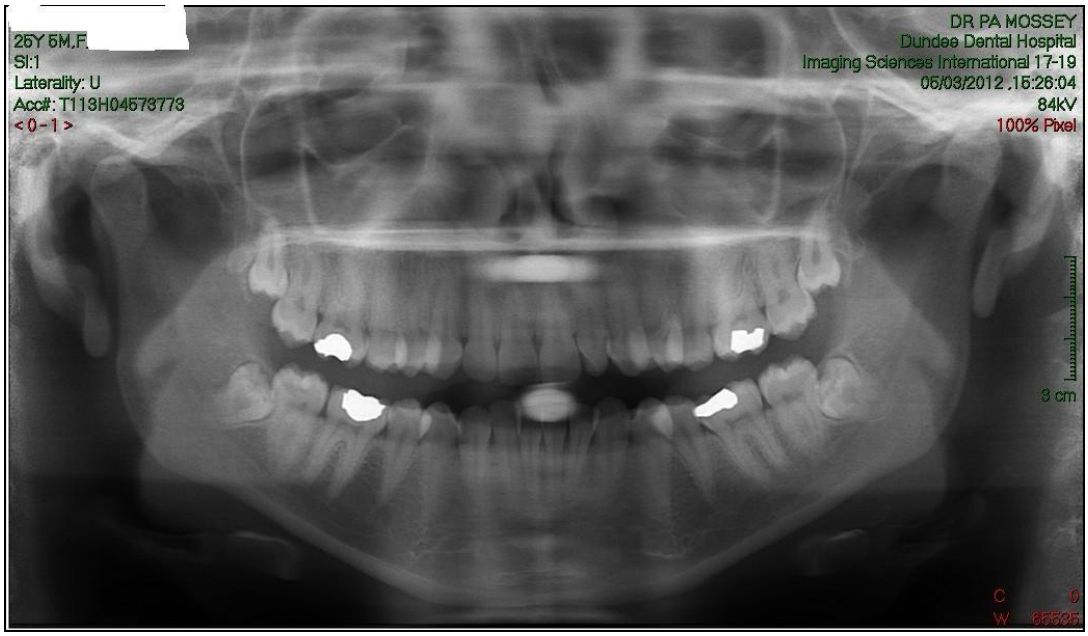
were determined by the consultant in charge of each subject's care. No standard set of radiographs were taken for each subject; some required no exposures, others had a combination of orthopantomograms (OPT), lateral cephalograms, periapicals or cone-beam CT (CBCT).

The vast majority of radiographs were taken by the Dental & Maxillofacial Radiology Department at Dundee Dental Hospital. These images were then saved onto the Picture Archiving and Communication System (PACS, Eastman Kodak Company, Rochester, NY, US), then saved as JPEG files and stored on a password protected NHS computer network.

Some radiographs were sent with referrals on CD-ROMs. Again, these electronic images were placed onto PACS which could then be saved as JPEG files Microsoft Paint (Microsoft, Redmond, California, US).

Paper print outs of the images were produced for each subject with all personal details removed and subject numbers the only means of identification (Fig. 8).

Figure 8 Digitised Orthodontic Radiographs

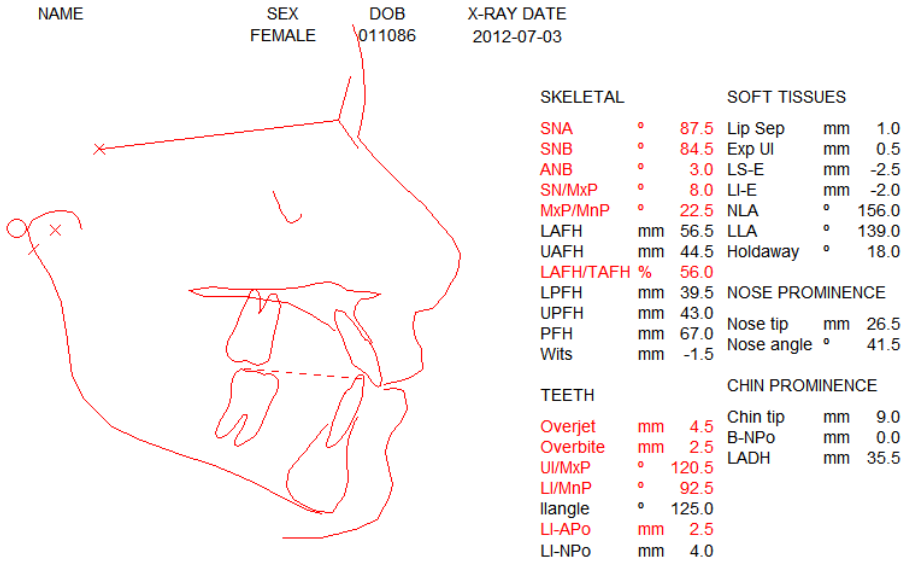


3.4.6 Traced Lateral Cephalograms

Each lateral cephalogram that was taken at the subjects' new patient appointments was digitised to produce a tracing using an Eastman analysis.[72] This was carried out using the Orthognathic Planning and Analysis (OPAL) computer program [(Harradine and Birnie, 1985) British Orthodontic Society, London, UK]. Tracings for each subject were saved onto a password protected NHS computer network with subject numbers used as the only identifiable feature (Fig. 9).

Paper copies of each tracing were also printed directly from the OPAL program, again only with subject numbers used to identify individuals.

Figure 9 Electronically Traced Lateral Cephalogram



3.4.7 Questionnaire

3.4.7.1 Design

Audit projects evaluating patient satisfaction of ongoing Orthodontic treatment have been an important aspect of clinical governance, ensuring quality of service. The basis for many questionnaires is the British Orthodontic Society (BOS) patient satisfaction survey (British Orthodontic Society, London, UK).[67] This was developed and validated by McNair et al.[65,66]

Unfortunately, no previous questionnaire has ascertained patient satisfaction with the referral process. Therefore, the questionnaire developed for this feasibility study was largely based on the BOS questionnaire with the addition of questions specifically geared towards assessing the subjects' views on the conventional referral process and their thoughts on potential benefits of electronic referrals.

Ease of reading was assessed using the Flesch Reading Score and Flesch-Kincaid Grade Level scores (Microsoft Word, Microsoft Corporation, Redmond, California,

US). Reading score and Grade Level Score were 53.2 and 8.8 respectively. This represented the reading age of a 14-15 year. With help from accompanying parents/guardians, it was anticipated that younger subjects would be able to complete the questionnaire.

The East of Scotland Ethics Service Research Ethics Committee reviewed and approved the questionnaire.

3.4.7.2 Completion and Content

Subjects were asked to complete the questionnaire (Appendix 4) when attending their first appointment in the Orthodontic Department at Dundee Dental Hospital following their clinical consultation.

Before the subjects were asked to answer any questions, they were presented with written information explaining the conventional process for referring patients into the Orthodontic Department. The passage also explained the possibility of sending electronic records from a high street dentist to the orthodontist. The passage concluded with an explanation of the purpose of the questionnaire and text about how to answer the questions appropriately.

Individual questionnaires were identified using only subject numbers. They asked the subjects' age, gender and postcode in order to assess if they were from an urban or remote and rural area.

They also asked whose idea it was to attend the orthodontist, how easy it was to get an appointment, how far they had to travel and what information was provided at the appointment.

The questionnaires also enquired about the subjects' views on their face-to-face consultation and whether they thought an electronic referral would have held an

advantage. The questionnaire aimed to garner the degree of enthusiasm of the subjects towards the prospect of teleorthodontics.

3.4.8 Summary

Following the subjects' initial appointment, it was anticipated that adequate records had been taken in order for the consultant participants to draw up treatment plans for each subject following the initial clinical assessment. The information came in the form of hard-copy records or digital records (Table 9). The digital records were available entirely on computers and in theory, remotely transferable from the GDP referrer to the orthodontist.

Table 9 Hard-copy and Digital Diagnostic Records

Hard-copy Diagnostic Records	Digital Diagnostic Records
Anonymised paper referral	Anonymised scanned referral
Paper intra-oral images	Electronic intra-oral images
Paper extra-oral images	3D electronic face scan
Plaster study models	3D electronic study models
Paper copies of radiographs	Electronic radiographs
Paper copy of lateral ceph tracing	Electronic lateral ceph tracing

3.5 Method

3.5.1 Clinical Procedure

Patients who had been referred to the Orthodontic Department of Dundee Dental Hospital were given an appointment on a new patient clinic on one of two dates, organised specifically for data gathering. In order for the potential subjects to have

time to consider taking part in the study, age appropriate PIS were sent to them, along with their letter informing them of their appointment time and date.

When the potential subjects attended their new patient appointment, the details of the study were again summarised to the patient and parent/guardian where appropriate. Any questions the potential subjects and parents/guardians had regarding the study were answered. Those individuals that met the inclusion criteria and wished to take part in the study were asked to complete three duplicate copies of an informed consent form for the over 16 year olds (Appendix 5) and an assent form for the 12-15 year olds (Appendix 6). The parents/guardians of the 12-15 year olds were also asked to complete a consent form.

Once consent had been obtained, clinical orthodontic records were taken. These included upper and lower impressions and wax bites for construction of plaster study models occluding in the subject's maximum inter-cuspal position. Intra-oral digital photographs, extra-oral stereophotogrammetry images and appropriate radiographs were also taken.

As well as records being taken, the subjects with help from parents/guardians where appropriate, were asked to complete the questionnaire. Data produced from the questionnaire was entered into an Excel database (Microsoft, Redmond, California, US). The hard copy questionnaires were destroyed following the entering of anonymised data.

3.5.2 Treatment Planning – Round 1

At the initial new patient appointments, two observers were present on morning clinics and two different observers present on afternoon clinics. Only two observers

were present on each clinic as it was felt that all four observers assessing patients on one clinic would not be conducive to efficient time management for the patients.

Each subject that agreed to take part in the study was examined clinically by the two observers present on the clinic. Following examination, the observers were asked to decide whether the subject required no treatment, surgical treatment or non-surgical treatment to manage their malocclusion best. They were also asked to include any additional comments as required (Fig 10).

Figure 10 Data Gathering Form

Data Gathering Form 1

Prof_____

Subject no.	No Treatment	Surgery	Non-surgical orthodontics	Additional comment
1				
4				
5				
6				
7				
8				
10				
11				
12				

3.5.3 Treatment Planning – Round 2

After a minimum one month wash out period, the observers were asked to complete the data gathering form again, this time all four observers making these decisions for every subject.

On this second occasion, instead of developing their treatment plan from a clinical orthodontic examination, the observers developed their plan from hard-copy diagnostic records. These consisted of paper referrals, colour print outs of intra-oral and extra-oral images, plaster study models, paper print outs of radiographs and lateral cephalogram tracings. All of these records were anonymised so that no names or CHI numbers were available to identify subjects. This procedure was carried out to reduce the possibility of the observers recalling their treatment plans for individual subjects they examined on clinic. Individuals were only identified by their subject number.

3.5.4 Treatment Planning – Round 3

Following at least a further one month wash out period, the third round of treatment planning was carried out.

This round of treatment planning was designed to mimic the planning achievable using digital diagnostic records, similar to the format used with teleorthodontics.

The digital records used for treatment planning in round 3 were: scanned original referral letters, electronic intra-oral images, 3D scans of the face, 3D scans of study models, copies of digital radiographs and tracings of lateral cephalograms available electronically.

All digital diagnostic records were anonymised and available on a password protected NHS computer network.

Each observer logged on to the network and was able to access the digital records in order to carry out their treatment planning, completing the same data gathering form as for rounds 1 and 2.

3.5.5 Treatment Planning – Round 4

In order to assess intra-observer treatment planning reproducibility one observer was asked to repeat the treatment planning for all patients following a further one month wash out period using hard-copy diagnostic records only, as was the case in round 2.

In addition, a different observer was asked to repeat the treatment planning process, again following a one month wash out period using digital diagnostic records, as in round 3.

3.5.6 Data Management

Following three rounds of treatment planning by all four observers and the additional round from observers 1 and 3, the results of their plans were entered into a database on Excel (Microsoft, Redmond, California, US).

This allowed intra- and inter-observer comparison of treatment planning decisions to be undertaken.

3.6 Statistical Analyses

Recording treatment plans developed by each observer for each round of data gathering allowed analyses of intra- and inter- observer reproducibility.

Table 10 shows the treatment plans developed by each observer using each format of diagnostic information. Observers 1 and 3 carried out additional rounds of treatment planning with observer 1 using the same digital records and observer 3 using the same hard copy records.

The data analyses were carried out using IBM SPSS Statistics software version 21 (IBM corp, NY, USA).

Table 10 Number of Treatment Plans Developed in Each Round of Data Gathering

	Diagnostic Information Format			
Observer	**Clinical**	**Hard copy**	**Digital**	**Additional**
1	11	27	27	27
2	11	27	27	
3	16	27	27	27
4	16	27	27	

Cohen's kappa coefficient was used to analyse each observer's reproducibility for the comparisons shown in Table 11. This table also shows that this same analysis was used to assess treatment planning reproducibility by observers 1 and 3 when the diagnostic data format remained the same.

Table 11 Treatment Plan Comparisons carried out by each Observer

Observer	Comparison		
1,2,3,4	Clinical vs hard copy	Clinical vs digital	Hard copy vs digital
1	Digital vs digital		
3	Hard copy vs hard copy		

Fleiss' kappa analysis was also used to analyse inter-observer reproducibility of treatment plans for hard copy and digital formats. Clinical treatment plans were not analysed as not all observers saw each subject clinically.

The results from the kappa coefficient analyses were interpreted as according to Altman,[73] illustrated in Table 12.

Table 12 Altman's Interpretation of Kappa Coefficient Scores

Cohen's kappa coefficient value	Level of agreement
0-0.20	Poor
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Good
0.81-1	Very good

Due to the relatively small number of responses provided from the questionnaires, descriptive analyses of these results were carried out.

RESULTS

4.1 Demographics

In total 27 subjects were recruited to the study. The ages ranged from 12-52 years with a mean of 25.1 years. Eleven (41%) subjects were male and 16 (59%) female.

4.2 Intra-observer Reproducibility

Table 13 illustrates each observer's reproducibility of treatment plans between each type of diagnostic record format. It shows that for each individual observer, reproducibility between clinical and hard copy records and hard copy and digital records are similar. However, for observers 2 and 3, reproducibility between clinical and digital records reduces.

Table 13 Intra-observer Reproducibility

	Diagnostic record format comparison (kappa coefficient)		
Observer	**Clinical vs hard copy**	**Hard copy vs digital**	**Clinical vs digital**
1	0.686	0.692	0.633
2	0.681	0.637	0.362
3	0.317	0.326	0.153
4	0.543	0.498	0.592

According to Altman's interpretation (Table 12), observer 1 showed good levels of agreement for each comparison of diagnostic record used. Observer 2 showed good levels of agreement when comparing clinical with hard copy records and hard copy with digital records, but only fair levels of agreement when comparing clinical and digital records. Observer 3 showed fair agreement when comparing clinical and hard copy records and hard copy with digital records, but poor agreement between clinical

and digital records. Observer 4 showed moderate agreement for each comparison of diagnostic record format.

4.3 Intra-data Reproducibility

As can be seen in Table 13, intra-observer agreement when comparing treatment plans developed using different forms of diagnostic record format ranged from 0.153-0.692. Table 14 shows Cohen's kappa coefficient for treatment plans developed by observers 1 and 3 when the diagnostic record format remained the same.

Table 14 Intra-format Reproducibility

Observer	Digital Format Comparison	Cohen's kappa coefficient
1	Digital vs digital	0.651
3	Hard copy vs hard copy	0.388

This result shows that change in diagnostic record format had little influence on Observer 1's treatment planning decisions as they had a consistently good level of agreement regardless of change in record format.

Observer 3's treatment plans showed similar levels of agreement when the record format remained the same and when clinical plans were compared with hard copy plans and hard copy plans were compared with digital plans. There was a fair level of agreement for these three comparisons. However, the level of agreement when comparing clinical and digital treatment plans was markedly worse than the intra-data reproducibility.

4.4 Intra-observer Treatment Plan Variations

Tables 15 to 18 illustrate intra-observer treatment planning variation when clinical diagnostic information is used compared to the digital diagnostic information. This shows the clinical relevance a change in the data format might have on the decisions made by the orthodontist. The numbers highlighted in red show the treatment plans altered due to the change in data format.

Table 15 Observer 1 Treatment Plan Variation

		Clinical			
		No tx.	Surgery	Ortho.	**Total**
Digital	No tx.	0	0	1	**1**
	Surgery	0	3	0	**3**
	Ortho.	0	1	6	**7**
	Total	**0**	**4**	**7**	**11**

Table 16 Observer 2 Treatment Plan Variation

		Clinical			
		No tx.	Surgery	Ortho.	**Total**
Digital	No tx.	2	1	2	**5**
	Surgery	0	0	0	**0**
	Ortho.	0	1	5	**6**
	Total	**2**	**2**	**7**	**11**

Table 17 Observer 3 Treatment Plan Variation

		Clinical			
		No tx.	Surgery	Ortho.	**Total**
Digital	No tx.	2	1	3	**6**
	Surgery	0	2	2	**4**
	Ortho.	1	2	3	**6**
	Total	**3**	**5**	**8**	**16**

Table 18 Observer 4 Treatment Plan Variation

		Clinical			
		No tx.	Surgery	Ortho.	**Total**
Digital	No tx.	3	0	1	**4**
	Surgery	0	7	2	**9**
	Ortho.	0	1	2	**3**
	Total	**3**	**8**	**5**	**16**

4.5 Inter-observer Reproducibility

The inter-observer agreement of treatment plans developed when using hard copy and digital records is illustrated in Table 19. Inter-observer agreement from clinical assessment is not included as observers did not assess every subject clinically. The results show that inter-observer agreement when using the hard copy records was moderate whilst using the digital records was fair.

Table 19 Inter-observer Reproducibility

Diagnostic Record Format	Inter-observer Agreement
Hard copy	0.490
Digital	0.377

Table 20 shows variation in treatment plans for each observer with each diagnostic record format.

Table 20 Treatment Plan Variation

	Observer											
	1			2			3			4		
Subject	C	H	D	C	H	D	C	H	D	C	H	D
1												
4												
5												
6												
7												
8												
10												
11												
12												
13												
15												
16												
17												
18												
19												
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21												
22												
23												
24												
25												
26												
27												
28												
29												
31												
32												

C – Clinical	H – Hard copy	D – Digital	No Tx	Surgery	Orthodontic Tx	Subject not seen clinically by observer

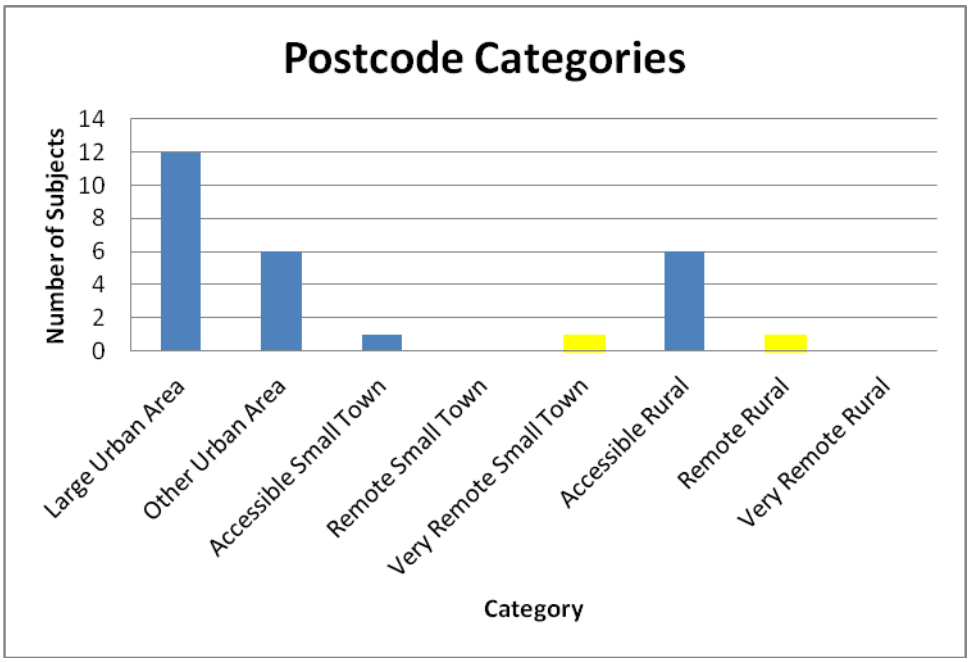
4.6 Questionnaire

All 27 subjects completed the questionnaire (Appendix 4). The purpose of the exercise was to establish the subjects' opinions on the process they went through in order to be seen on the orthodontic clinic, their experiences at their initial appointment and also their thoughts on the potential benefits of teleorthodontics. Demographic data, including postcodes were also acquired allowing any differences in responses between subjects from a remote and rural area to be highlighted when compared to those form an urban area.

As mentioned, ages ranged from 12-52 with a mean of 25.1. Sixteen subjects were female and 11 male (59:41%)

Figure 11 shows the number of subjects living in different postcode category areas as outlined in Figure 1. The majority of subjects live in urban areas whilst only two subjects, as highlighted in yellow, reside in a remote and rural area.

Figure 11



Postcode Category According to Scottish Government

Figure 12 shows that in the largest number of cases it was the general dental practitioner (GDP) that initiated the referral of the subject for an orthodontic consultation, with the subjects themselves making a significant contribution.

Figure 12

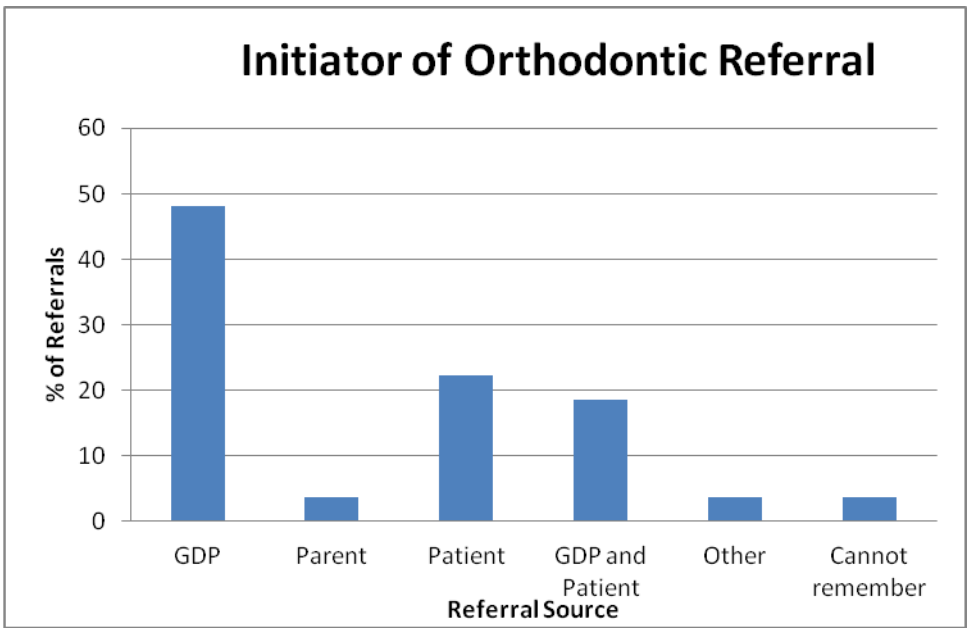
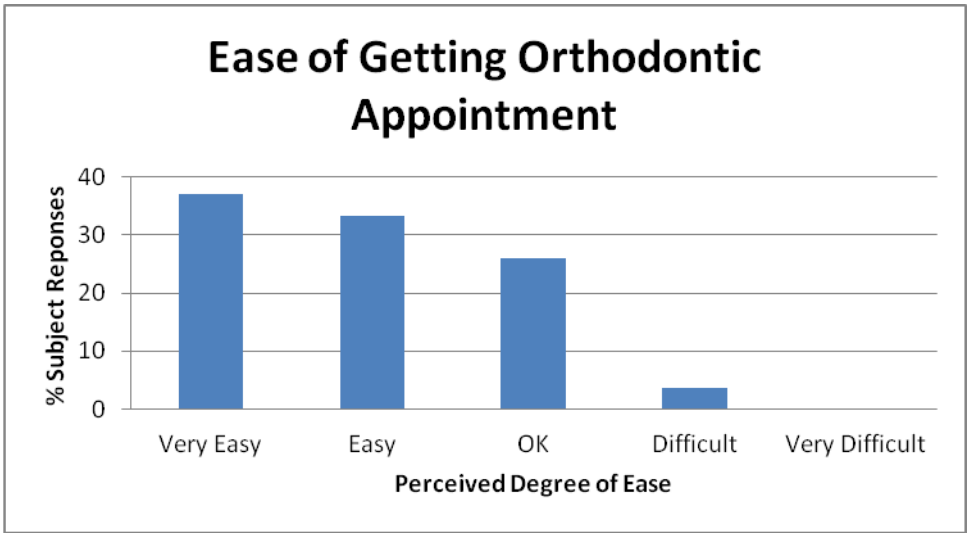


Figure 13 shows that there was little difficulty in receiving an initial orthodontic appointment.

Figure 13

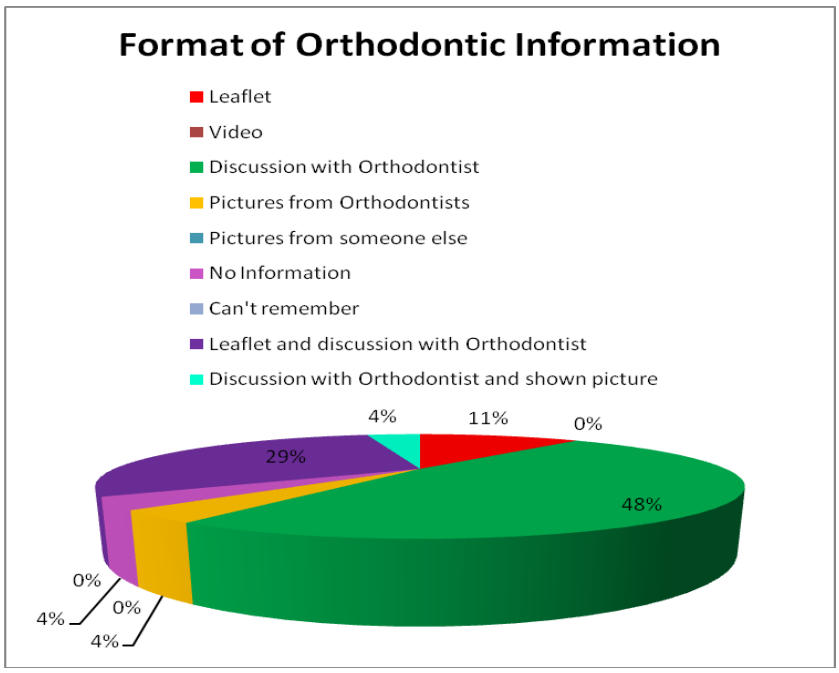


Subjects waited a mean of eight weeks from their referral to their initial orthodontic appointment. This ranged from one to 32 weeks.

The mean number of miles subjects travelled to attend their orthodontic consultation was 14 with a range of 1 to 40.

96% of subjects received adequate information at their orthodontic appointment. Figure 14 shows that the majority of this information was provided via a discussion with the orthodontist.

Figure 14



85% of subjects had all of their questions answered completely at the initial appointment. The remaining subjects had their questions partially answered.

89% of subjects felt that the orthodontists paid them enough attention and 88% agreed with the orthodontist's findings. 70% were advised at the initial appointment to have orthodontic treatment and 74% wished to have treatment carried out following their consultation.

74% of subjects felt that seeing an orthodontist face-to-face was extremely important to discuss their case and 93% felt that the face-to-face consultation provided a good quality of care, Figure 15 shows that the subjects were satisfied with this format.

Figure 15

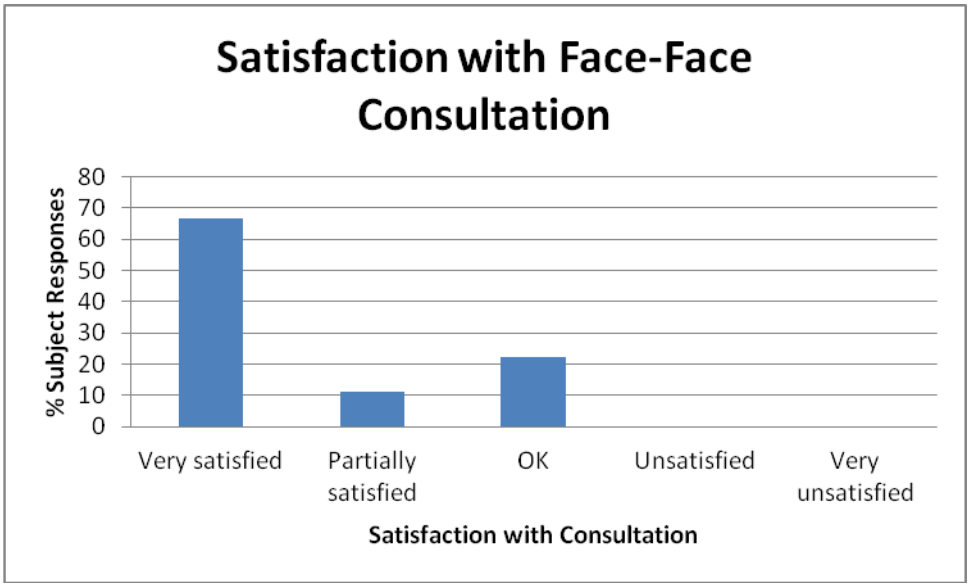
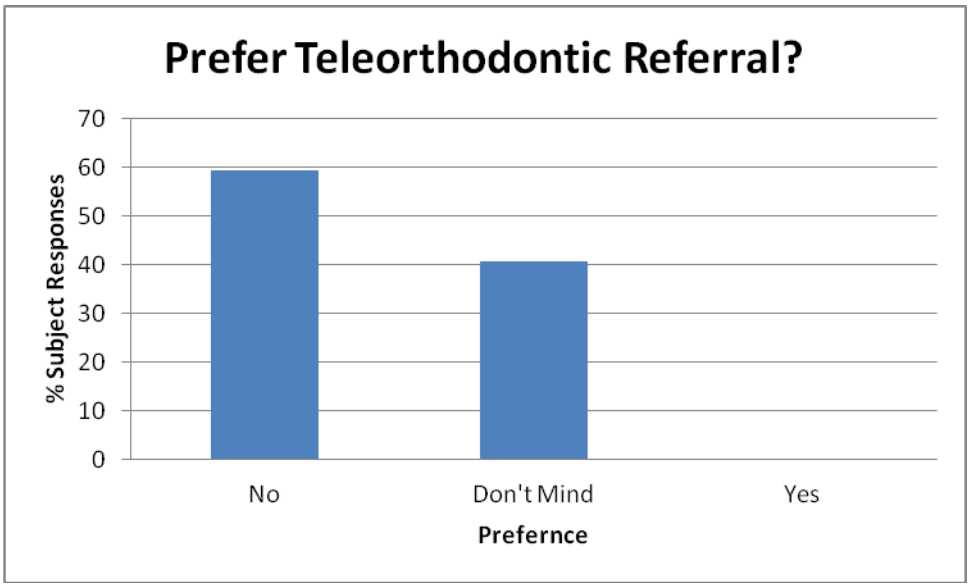


Figure 16 illustrates that the majority of subjects would not prefer their case to be sent to the orthodontist via a teleorthodontic referral. A substantial proportion did not mind if this was the case, however no subject preferred his or her referral to be sent this way.

Figure 16



Most subjects believed that e-referrals would save time and there was an almost even split between the subjects who thought that the process would save them money and inconvenience (Fig.17). Almost a quarter of subjects thought that a referral made using teleorthodontic technology would enable an orthodontic opinion to be provided more easily than following the conventional method (Fig. 18).

Figure 17

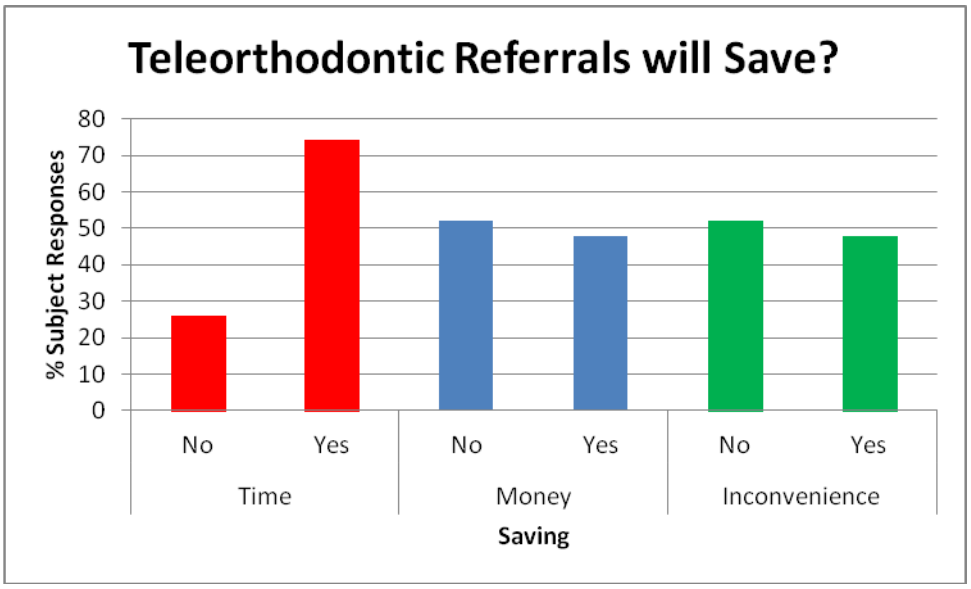
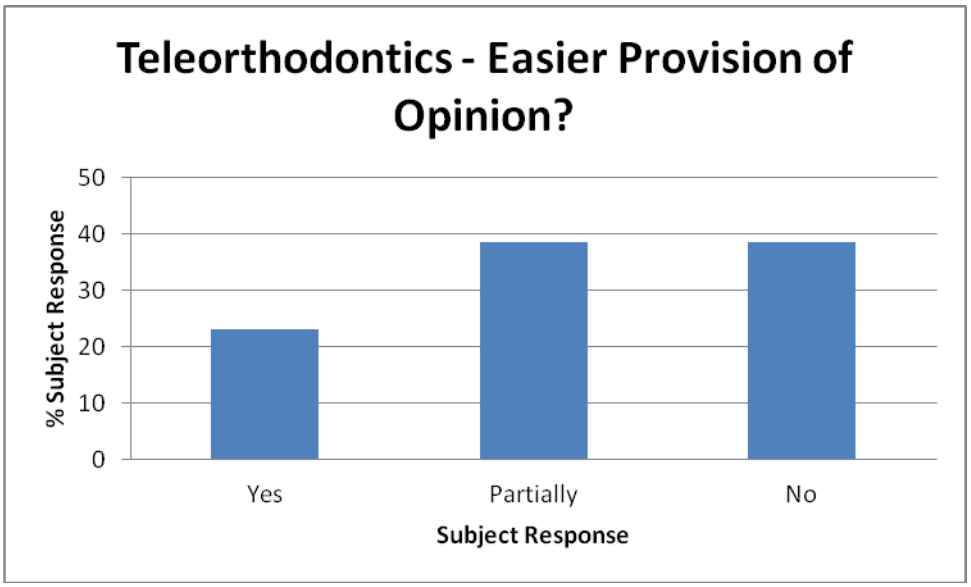


Figure 18



DISCUSSION

5.1 Subjects

5.1.1 Sample Size

In an attempt to carry out a study with sufficient power to investigate the influence of diagnostic information format on treatment planning decisions, the possibilities of an *a priori* sample size calculation being carried out was undertaken. A group of 14 local orthodontists on the UK specialist list were presented the results of a survey[74] that had found the percentage of patients receiving growth modification, orthodontic only or surgical treatment in the UK in 1996. They were then asked what changes to the percentages would be clinically important. The six responses (Appendix 7) showed that a small change in the percentage of patients receiving surgical treatment would be clinically important due to the increased risk of morbidity and mortality associated with this care pathway.

The responses to this question were presented to a statistician who informed the investigators that the numbers of subjects required to produce a sufficiently powered study would be well beyond the capacity and resources available for the scale of investigation envisaged. The investigation was then planned as a feasibility study with a more manageable cohort of 25-30 subjects. This study was still felt to be worthwhile, as it would help develop a plan for a potential, larger scale investigation in the future.

In total 27 subjects were recruited. Due to the delay in receiving written confirmation of ethical approval on the first day of data gathering, informed consent could not be accepted from the potential subjects. This meant that the subjects had to return for a subsequent appointment, following receival of ethical approval before they could be recruited into the study. Unfortunately four subjects did not return, therefore they

were lost from the study. One subject was not recruited because they made it clear early in the consultation that they did not desire Orthodontic treatment. In total five potential subjects were lost from the study.

All other subjects that were approached to take part in the study agreed to provide consent and were recruited.

5.1.2 Exclusion Criteria

Potential subjects were excluded from the study if they had previously undergone orthodontic treatment. This was because previous extractions, growth modification, camouflage, demineralisation, lack of retainer wear etc. may influence the observers' perceptions of treatment need significantly.

An original referral was required to be included in the clinical notes for each subject as this additional information may provide a substantial contribution to an observer's plan. Therefore, each subject's original referral was made available at all stages.

Patients with cleft lip/palate or congenital craniofacial anomaly were excluded as it was felt that all observers would agree that treatment would be required for these patients. It was thought very unlikely that any of these patients would be referred to a routine new patient clinic as they would be receiving ongoing care and this was in fact the case.

No patients under the age of 12 or in the early mixed dentition were included as definitive treatment plans could not be drawn up at this stage of development.

Patients unable to understand the details of the investigation were also excluded as informed consent acquisition could not be achieved.

5.1.3 Residence

The subjects were recruited from the pool of patients referred to the orthodontic department of Dundee Dental Hospital. This was advantageous as it allowed the patients to attend the department with as little disruption to their referral and consultation as possible. This also meant that four consultants would be available as observers within the department.

There was no budget available to recruit subjects over and above those that would already be attending the department. Initially, it was planned that subjects could be recruited from those attending Perth Royal Infirmary as well as those attending in Dundee. This would have been advantageous as a greater proportion of subjects attending Perth Royal Infirmary reside in remote and rural areas, meaning that the subjects recruited would have represented a wider range of the urban and remote and rural population of Scotland. This would have provided a better representation of the remote and rural population's opinion of the potential benefits of teleorthodontics, which is desirable as it is envisaged that it is this population that would benefit most from the technology.

Unfortunately, subjects could not be recruited from Perth Royal Infirmary as not all of the digital records could be gathered in this centre and only one consultant routinely works in this setting. It was not thought appropriate for one observer to assess the subjects clinically whilst no other observer had this opportunity. This may have led to recall bias in favour of the observer who had seen the patients clinically.

5.2 Methodology

5.2.1 Clinical

Those individuals on the orthodontic department waiting list that were seen as potential study subjects were sent a Patient Information Sheet (PIS) explaining details

of the study along with their appointment letter. Different versions of the PIS were sent for those individuals aged 12-15, 16-18 and over 18s. The language used in each PIS became gradually more detailed as the reader age group increased. Potential subjects aged 12-15 also had an over 18 PIS sent with their appointment letter so that parents/guardians understood what was involved in the study. The language used in the different PISs was deemed as acceptable by the East of Scotland Ethics Service Research and Ethics Committee.

It was thought very important that the PIS was sent prior to the potential subjects attending their first appointment as it was hoped that the subjects could give their consent to take part in the study at the initial appointment. This would mean that all data could be gathered from the patient in a single episode. For this to be achievable it was felt that potential subjects should be given the opportunity to consider whether or not to take part in the study with an adequate 'cooling off' period prior to being asked to give consent to take part. This would not have been possible if the subjects had been presented details of the study, then asked to give consent immediately afterwards at the initial appointment.

Unfortunately, on the first day of data gathering, written confirmation of ethical approval had not been received, despite assurances that it had been granted. Because of this, potential subjects could not provide consent at their first appointment. In addition, they could not complete questionnaires as this was an additional process that would not routinely have been carried out if the study had not been ongoing. However, clinical examinations and record gathering could be carried out, as this would happen routinely.

In order to gain consent and enable completion of the questionnaire, the potential subjects from the first day of data gathering had to be seen on a second occasion, once written confirmation of ethical approval had been received. This however relied upon

potential subjects attending a further appointment, which some individuals may have been less likely to do if they had been told at the initial appointment that they did not require orthodontic treatment or when they were informed of what the treatment involved. This may have meant that subjects recruited to the study from the first day of data gathering disproportionately required treatment, as they returned for a second appointment. Four potential subjects from the first day of data gathering did not return, which unfortunately resulted in sample attrition. One potential subject from the second day of data gathering was also not included in the study, this was because they stipulated early in the consultation that they were not interested in orthodontic treatment and it was felt that taking records would not have been appropriate.

The logistical challenge of arranging patient attendance, record gathering, consultant timetable co-ordination and clinical examination was significant. It was not felt that the time required for all four of the observers to assess each subject clinically was practical for consultant or patient. Therefore two observers assessed subjects clinically in the morning and the remaining observers assessed the subjects in the afternoon. The ideal scenario would have incorporated all observers assessing all subjects clinically, allowing more thorough intra-observer treatment plan reproducibility analysis, but greater resources would have been required than were available.

5.2.2 Digital Records

Digital orthodontic records have gradually become incorporated into routine orthodontic practice in the form of digital photographs and radiographs. In the example of lateral cephalograms these can also be traced digitally.

In order for all diagnostic information to be in a digital format, enabling teleorthodontics to be carried out, referrals, extra-oral images and study models must also be able to be presented digitally.

Referrals can be scanned or emailed without any specialised equipment required. To enable an accurate 3d extra-oral image to be created however, specialised equipment is currently required. For this study, 3dMD technology was used to carry out a stereophotogrammetry scan of each subject. This proved to be a very quick and easy procedure, taking less time than extra-oral photographs. Gwilliam,[46] Plooij,[47] and Aynechi[43] confirm the accuracy of this technology (Table 5).

The software used in this study did not allow zoom or full movement of scanned images, requiring the observer to wait for the image to rotate slowly for the full extent of the scan to be visible. As mentioned, shadowing from hair resulted in incomplete imaging. In addition, the software version used did not allow lateral cephalogram integration into the image and surgical prediction which may be desirable in some cases.

Digital study models were produced from plaster study models. Initially it was hoped that these models could be digitised using a NextEngine laser scanner (3D scanner HD, www.nextengine.com). It was anticipated that these scans would produce clinically acceptable digital models, hypothetically having little influence on treatment planning decisions as described in papers by Santoro,[31] Quimby,[32] Keating,[34] Abizadeh[36] and Stevens[37] (Table 4). Unfortunately, following a period of time attempting to scan the models, it was evident that an articulating arm was required to enable full, high quality imaging of the study models. Time and financial constraints meant that an alternative method of digitising the models had to be found. The decision was made to scan the study models using a cone-beam computed

tomograph (CBCT). Kau[38] and Tarazona[39] used CBCT to produce digital study models directly from scans of the subjects which were found to be clinically acceptable alternatives to digital models produced from conventional plaster models. Wu[40] and Lv[41] found that despite digital study models, derived from CBCT scans, producing systematically smaller reproductions, this did not result in a clinically significant difference. Therefore, it was felt that this was the most efficient way of gathering this diagnostic record in these circumstances.

Visualising the digital study models was not ideal, as it required multiple cursor commands in order to load a study model for an individual subject. Load time for each image was very long and the images were only available on one computer as this was the only machine with the required software installed. The computer was located adjacent to the orthodontic clinic. This meant that the study model imaging process was far from user-friendly and the setting for the treatment planning was not peaceful.

If study model digitisation had been carried out using a dedicated scanning system the process would likely have been faster, more user-friendly and could have been carried out on any computer with all data available. Unfortunately, this was not the case in this investigation and the treatment plans developed from digital diagnostic records may not have accurately mimicked what would be available through a fully developed teleorthodontic system.

5.2.3 Questionnaire

The questionnaire used in this study was designed to assess patient satisfaction with the referral process and initial consultation. It was also hoped to assess patient opinion regarding the possible benefits of teleorthodontics, ideally highlighting if there were any differences of opinion between patients from urban or remote and rural areas.

No questionnaire had previously been produced with the aim of gathering this information; therefore, this feasibility study's questionnaire was developed using the British Orthodontic Society's (BOS) patient satisfaction questionnaire[67] as a basis. It was not felt that the time and resources required to fully validate the questionnaire used in this study would have been implemented efficiently, especially as it was not the sole aim of the project. McNair[65,66] showed that a large amount of work had been put into developing the BOS questionnaire and even then, it was not full validated, yet still used throughout the country in various audit projects.[68-71] It was therefore thought that developing the feasibility study's questionnaire closely to McNair's format, with additional relevant questions, would allow worthwhile data to be gathered from the subjects.

McNair's questionnaire had a Flesch Reading Score of 79.8 and Flesch-Kincaid Grade Level score of 4.8, equating to a suitable reading age of 10. The questionnaire developed for the feasibility study had a Flesch Reading Score of 53.2 and Flesch-Kincaid Grade Level score of 8.8 (Microsoft Word, Redmond, California, US). This equates to a reading age of 14-15, which is older than desired. However, it was anticipated that any subjects under the age of 16 would be accompanied by their parent/guardian who would be able to help with the questionnaire and investigators were on hand to assist if any questions were not clear. Furthermore, the questionnaire was deemed as acceptable by the ethics committee.

5.2.4 Treatment Plans

In this investigation, the observers were asked to develop treatment plans for the subjects using different diagnostic records formats. The observers were only given three, very broad treatment options: no treatment, non-surgical orthodontic treatment and surgery meaning orthognathic or surgically assisted rapid palatal expansion, but

not canine exposure or supernumerary removal, for example. These treatment options are broader than those used by Han[60] and Whetten.[62] This was thought worthwhile because there was only a small sample size and if treatment plans were too intricate, their reproducibility would be less likely and very little relevant comparable data would be produced. Due to the small numbers of subjects, broad trends had to be looked for.

At least a one month wash out period was held between each round of data gathering to minimise the risk of recall bias from the observers. This is consistent with Han[60] and Whetten.[62] Devereux's[61] observers had at least a two month wash out period and Rheude[63] allowed only 30 minutes.

Ideally, a longer wash out period would have been used, particularly due to the broad treatment plans available in this feasibility study. However, time constraints meant that this was not an option. Anecdotally, the observers in this study admitted to very little recall of the cases between each round of data gathering.

Each observer completed data gathering rounds 1, 2 and 3. As previously stated, not all subjects could be assessed clinically by all observers. A fourth round of data gathering was carried out by two of the observers to assess treatment planning reproducibility when the diagnostic data format remained the same. This was carried out in order to produce a reference to the intra-observer results when the record format changed. This gave an indication as to whether lack of reproducibility of treatment plans was due to the change in record format or simply random observer error.

Preferably, all four observers would have carried out at least one further round of data gathering in order to compare intra-format reproducibility, including clinical treatment planning, but observer and subject time constraints did not allow this.

5.2.5 Results Analysis

Intra-observer treatment plan reproducibility was analysed using Cohen's kappa coefficient. This analysis is thought to be more robust than stating percentage agreement as it is meant to take into account agreement occurring simply due to chance. This is consistent with Whetten,[62] but inconsistent with Han,[60] Devereux[61] and Rheude.[63] In order to analyse inter-observer results, a test to assess reproducibility between multiple observers was required and Cohen's kappa coefficient is unable to do this. Fleiss' kappa analysis was used following discussion with the statistician.

Descriptive analysis of the data from the questionnaire was carried out as it was thought that any attempt to look for trends with such a large variety of possible answers and such a small number of subjects would have been futile.

5.3 Findings

5.3.1 Intra-observer Reproducibility

Intra-observer treatment planning reproducibility when comparing different formats of diagnostic records produced some very interesting results (Table 13). When comparing clinical with hard-copy records and hard copy with digital records, observers 1 and 2 showed good reproducibility, observer 4 moderate and observer 3 fair. Levels of consistency were maintained by observers 1 and 4 when comparing clinical with digital treatment plans, but observers 2 and 3's reproducibility fell to fair and poor respectively. The intra-observer treatment plan reproducibility range of κ=0.153-0.692 is generally unfavourable when compared to other papers investigating treatment plan consistency (Table 2). Ribarevski[21] found intra-observer agreement, when deciding on extraction/non-extraction decisions ranged from κ=0.54-0.96. Lee[22] found intra-observer agreement of treatment plans and diagnoses ranged from κ=0.24-0.90. Mandall[20] found intra-observer agreement of acceptance of orthodontic referrals

from photographic records ranged from κ=0.34-0.90. Of most relevance to this investigation, Whetten[61] produced kappa intra-observer agreement figures when comparing treatment plans made on plaster study models compared to those on digital models (Table 7). Good levels of agreement ranging from κ=0.777-0.870 were found, again making the reproducibility of treatment planning in this study appear low.

Assessing intra-data treatment plan reproducibility provided an indication of the influence a change in record format had on the treatment plans developed. For example, if the kappa coefficient scores were similar when the record format remained the same; compared to when the formats changed, this would indicate that the change in format had little influence on the treatment plans and comparative differences were due to observer variance. The results of this investigation show that observer variation appears to contribute to the relatively low intra-observer treatment plan reproducibility. This is evident in Table 14, which illustrates that even when diagnostic record formats remain the same, treatment plan reproducibility does not change markedly. Therefore, the change in the diagnostic record format did not appear to have an effect on treatment planning. The exception to this was when comparison was made of treatment plans developed clinically and digitally by observers 2 and 3.

The reason for this reduction in agreement is not particularly obvious as reproducibility of treatment plans for both clinical and digital formats when compared to hard-copy records are very similar for each individual observer. In addition, reproducibility of treatment plans when comparing clinical and digital formats were very similar to the other comparisons for observers 1 and 4, indeed, the reproducibility of this comparison for observer 4 was their greatest (κ=0.592).

A possible explanation is the lack of familiarity with using digital extra-oral images and study models for treatment planning, compared to the more routine process of

assessing the subjects clinically or from their hard-copy records. Rheude[63] noted that as observers grew more accustomed to using digital study models, less diagnostic variation was found. If the observers spent more time using the digital diagnostic records there is the possibility the treatment planning consistency, when compared to clinical assessment would improve.

Following discussion with the observers, it was noted that the digital treatment planning process was not particularly user-friendly. The inability to have multiple diagnostic records on the screen at once; multiple windows open at any one time, potentially leading to subject number confusion and the long load time for digital study models all may have contributed to the less consistent treatment planning. Indeed, observer 3 mentioned that due to the long period of time required to load a digital study model, they looked at all other diagnostic information available first, then only assessed the study models if they felt this was necessary.

This raises an interesting point regarding the importance of study models in treatment plan decision making. Han[60] found that 55% of treatment plans drawn up after assessing the study models did not change regardless of subsequent records provided. It is an interesting thought whether the importance of the study models in this case is due to the models themselves or simply that they were the first records provided in the data gathering sequence. For example, would a similar percentage of treatment plans be consistent if photographs or radiographs had been provided first? Furthermore, do orthodontists develop a treatment plan from the first record assessed, then simply use subsequent records to justify their plan?

Observer 3's Cohen coefficient for treatment plan agreement between clinical and digital records of 0.153 would suggest that study models do have an influence on treatment planning consistency and should be used in each case.

The intra-observer treatment plan reproducibility from two of the observers rejects the initial part of the first null hypothesis; that orthodontic treatment planning is not affected by diagnostic record format. However, the null hypothesis could be argued to be supported by the results from the other two observers. This highlights the variation in treatment planning between individuals.

5.3.2 Intra-observer Treatment Plan Variation

Consistency in treatment planning is interesting to note, but the most relevant part of any research is its clinical impact. For this feasibility study, the most important analysis is the variation of treatment plans developed clinically versus those developed digitally. This is because, if teleorthodontics was to be used routinely for remote and rural patients, orthodontists would rely on digital records as opposed to seeing the patient face-to-face. From a treatment aspect, the most important variation would be any inconsistency in surgery decision making due to the associated morbidity and mortality.

Tables 15-18 illustrate that observer 1's decision making is quite consistent with only two decisions made digitally different from those made clinically. Of note is that one decision made digitally was orthodontics only whilst clinically the plan was surgery.

Observer 2 was less consistent. In this case, one subject deemed as requiring no treatment when assessed digitally and another planned to have orthodontic treatment only, were planned to have surgery on clinical examination.

Observer 3 had a greater degree of variation still. From digital records, they felt that two subjects required surgery, but on clinical assessment they planned orthodontic treatment only. In contrast, when examined clinically the observer concluded that two subjects needed surgery, but when assessed digitally they had planned orthodontic treatment only.

Observer 4 showed less overall variation, but from digital records, they planned surgery for two subjects, but orthodontic treatment clinically. Alternatively, from the clinical examination they planned surgery for one subject, but orthodontics from the digital records.

These results showed that if these subjects had been assessed digitally, but not clinically, four might have been put forward as potential surgical cases that may not have been if seen clinically. This could have had a marked effect on the care provided to the patients.

It is worthwhile re-iterating that subjects seen by observers 1 and 2 are different from 3 and 4 as different subjects were assessed clinically by different observers. The varying surgery/orthodontic decisions made by observers 3 and 4 may have been due to more surgical 'border line' cases. However, further investigation of individual cases is out with the scope of this study.

Table 20 illustrates patterns of treatment plans developed by each observer using the different record formats and the variation of treatment plans between the observers.

It shows that when observers 1, 2, and 3 decided that a subject should have surgery, they usually concluded this when using hard copy records as their diagnostic information. However, for corresponding subjects, surgery was less consistently chosen when the diagnostic information was provided in the digital format. Observer 4 showed greater variation in surgical decisions between clinical and hard copy formats.

When using digital records, observers 2 and 3 were less likely to recommend subjects proceed with orthodontic treatment than when hard copy records were used. In contrast, observers 1 and 4 were less likely to recommend treatment when using the hard copy record format.

The table shows that there is variability in treatment plans developed regardless of whether the observers planned the subjects' treatments clinically or only using hard copy and digital records.

5.3.3 Inter-observer Agreement

Fleiss' kappa analysis was used to assess inter-observer agreement of treatment plans developed using hard-copy and digital records (Table 19). Inter-observer agreement using hard-copy records was moderate (κ=0.490). This shows greater inter-observer agreement than Ribarevski[21] when making extraction/non-extraction decisions using full patient records (κ=0.38). The results are similar to Lee[22] when case vignettes were used for diagnosis and treatment plan (κ=0.54 Table 2). However less than those produced by Whetten[62] when assessing agreement for surgery, extractions and auxiliary appliance using plaster models (κ=0.671, 0.626, 0.672, Table 7).

Inter-observer agreement when digital records were used for treatment planning was only described as fair (κ=0.377). The reason for the reduction in agreement from hard-copy use may again be due to the lack of familiarity in using the technology and the deficient user-friendly presentation of the records. It is conceivable that observers would constantly develop the same treatment plans for certain subjects if all records were available for easy amalgamation. However, repeated shifting from one record to another may disrupt this process, leading to confusion and atypical treatment planning decisions.

The results from this study are similar to those from Mandall[20] where a form of teleorthodontics (photographic records) were used to test acceptance of orthodontic referrals (κ=0.37, Table 2). However, when compared to Whetten's[62] surgery, extraction and auxiliary appliance use treatment planning agreement between digital and plaster study models, the results from this feasibility study are quite disappointing

(κ=0.549, 0.570, 0.539, Table 7). A possible reason for Whetten's greater agreement may have been the use of dedicated digital imaging software, which resulted in less confusion and allowed the digital treatment planning process to more closely resemble the routine treatment planning process.

This feasibility study's results reject the second part of the first null hypothesis as changing the record format clearly did result in a difference in the inter-observer treatment plan reproducibility.

5.3.4 Questionnaire

The questionnaire used in this feasibility study was designed to assess the subjects' opinions regarding their referral, thoughts of their initial appointment and their opinions on the potential benefits of teleorthodontics.

With regards to the ease of organising their initial appointment, 96.3% of subjects were satisfied (Fig. 13). Indeed, only one of the 27 subjects had any difficulty. This compares favourably to audits carried out by Nasr[68] and Balakrishnan[69] who found only 53% and 76% of patients could arrange appointments when it suited them, respectively (Table 8). However, it would be anticipated that a higher proportion of subjects would be able to make arrangements to attend a one-off consultation appointment, as in this feasibility study, as opposed to routine orthodontic appointments which need to be arranged with specific consultants every six to eight weeks, as was the situation for these audits.

At the initial consultation 96% of subjects felt that they received adequate information. This is a similar finding to those from Nasr,[68] Balakrishnan[69] and Sees[71] who all found patient satisfaction with information provided to be over 90%. Lo and

Yap[70] found only 74% of respondents were happy with the amount of information provided to them at each appointment (Table 8).

The majority of subjects in this investigation received this information through discussion with the orthodontist, often coupled with provision of leaflets (Fig. 14).

Reassuringly no subjects were unsatisfied with their face-to-face consultation, with two thirds of subjects very satisfied (Fig. 15).

Subjects felt the opportunity to discuss their case with an orthodontist face-to-face was extremely important in 74% of cases. This factor is likely to have contributed to the finding that almost 60% of subjects would not prefer their referral to be sent via teleorthodontics, while no subjects actively preferred this option (Fig. 16). Despite this, the majority of subjects did believe that teleorthodontics had the potential to save them time and a high proportion believed it would save them money and inconvenience (Fig. 17). Almost a quarter of subjects believed the use of teleorthodontic technology would allow easier provision of an orthodontic consultation (Fig. 18), but the reassurance of the patient-clinician interface is clearly sought.

It was hoped that this questionnaire might be able to provide an insight into any differing opinions regarding the use of teleorthodontic referrals between patients living in urban areas compared to those from remote and rural communities.

From the postcode scores provided by the subjects, it was evident that only two subjects were regarded as coming from a remote area as described by the Scottish Government Urban/Rural Classification (Fig. 1). Six subjects were defined as coming from ‘accessible rural’ areas (Fig. 11), but it was not felt that these subjects were suitably remote from the orthodontist to provide appropriate opinions on the use of

teleorthodontics for remote and rural patients as a drive of less than 30 minutes was not thought to be excessive.

When focusing on the two subjects from remote and rural areas, it is evident that neither would mind if their referral was sent using the teleorthodontic technology as both thought that this format would make it easier for them to receive an orthodontic opinion. Both thought that using this technology could save them time and money with one feeling that it would result in less hassle.

This indicates that if subjects were recruited from more remote and rural areas, there is the possibility that there may be a more positive outlook on the use of teleorthodontic referrals. However, it is likely that, given the opportunity, most patients would prefer the option of seeing an orthodontist face-to-face.

Unfortunately, the second and third null hypotheses could neither be accepted nor rejected due to the lack of remote and rural patients recruited to the study. It was not possible to establish any difference in opinion between urban and remote and rural patients regarding their satisfaction with the conventional consultation system or perceived benefits of digital record use in remote referrals.

5.4 Review of Feasibility Study

5.4.1 Strengths

The main strengths of this feasibility study have been its originality and its relevance. Research into teleorthodontics is at an early stage, however a number of papers have been published concluding that the technology used to implement teleorthodontic applications find no clinical difference from routine hard copy records. Digital referrals, photographs and radiographs are commonly used. Stereophotogrammetry

and digital study models are also being developed in order that a 'virtual patient' could be constructed and applied to teleorthodontics in the future.

Previous studies have found that for the purposes of orthodontic treatment planning, digital records are an acceptable alternative to hard-copy records.[61-63] This feasibility study is unique as it not only compares treatment plans developed using hard copy and digital records, but also from clinical examinations.

The potential benefits of teleorthodontics are particularly relevant to remote and rural areas of Scotland where the use of ever more available digital technology could allow much easier orthodontic consultation to be carried out. This feasibility study has been the first to attempt to gauge patient opinion on the potential use of teleorthodontics and if those individuals from remote and rural areas appreciate the potential benefits more than patients where access to orthodontic consultation is easier.

5.4.2 Weaknesses

The resources available to carry out this feasibility study entirely as desired were unfortunately limited. A workable number of subjects were recruited to the study, however due to the written confirmation of ethical approval arriving later than anticipated; a small number of viable potential subjects could not be consented to take part.

The subjects were recruited from one centre in order that observers had access to carry out clinical examinations. This meant that the majority of subjects were from urban areas. Ideally, subjects would also have been recruited from at least one more centre where more patients were likely to live in remote and rural areas. This would allow better comparison of urban and rural opinions on teleorthodontics.

Due to time constraints on clinic and observer availability, only two of the four observers could develop clinical treatment plans at each of the data gathering sessions. This meant that full intra-observer clinical treatment planning agreement could not be carried out because the observers did not examine every subject clinically. An assessment of inter-observer agreement of the clinical treatment plans was also not possible between all four observers. It was possible to assess inter-observer agreement of treatment plans following clinical examinations between observers 1 and 2 and also 3 and 4, however this was not carried out as it was desirable to assess inter-observer agreement for all subjects recruited.

Clinical assessment of subjects by some observers and not others may also have resulted in recall bias in treatment plan reproducibility, despite the one month wash out period. For example, the observer may recall a subject's attitude towards treatment at the initial consultation. This could then affect subsequent treatment plans that may have differed if developed purely from diagnostic records.

The use of digital records was designed to replicate the use of teleorthodontic technology to treatment plan cases. The majority of the technology used was acceptable, however problems were associated with the digital study models. The laser scanner anticipated for use, produced scans of such poor quality that an alternative had to be found quickly. The use of the CBCT provided a solution, however this practice does not replicate the technology that would be used in teleorthodontics. Furthermore, the digital models were only available on one computer and their retrieval was time consuming. No other records could be seen when the models were on screen and this led to confusion regarding which models corresponded to the remaining records. A tutorial ensuring acceptable ability of using the digital records for the observers would have been desirable to limit gross outlying

treatment planning decisions derived from the lack of user-friendliness of the digital technology.

There was a risk of a systematic error due to the observers examining the diagnostic information of the subjects in the same order, this had the risk of enabling recall of previous treatment plans resulting in greater treatment planning agreement. This was not the case in this study as the agreement was not particularly strong. However, the risk systematic error could have been reduced by randomising the order of subject information provided and also the formats used for each observer.

5.4.3 Implications for Clinical Practice

The results of this feasibility study have shown that for some observers, there is greater variation in treatment plans developed digitally compared to those developed clinically or with hard copy records. However, as technology becomes more user friendly and observers become more familiar with the process of treatment planning with digital records, it would be hoped that this variation reduces.

It is likely that the majority of patients would prefer a face-to-face consultation, but remote and rural patients may be more open to the potential of digital technology being used for teleorthodontic referrals. There is the possibility that using this technology could save them time, money and inconvenience of making a long journey for a consultation. This is particularly relevant, as a large proportion of referrals are known to be inappropriate in the first place. However, in order for this remote referral process to be feasible, conventional records require to be converted to digital format, most likely by the patients' general dental practitioner. The time and cost implications in order for this to be viable would require to be thoroughly assessed compared to the benefits to the remote and rural patients.

5.4.4 Summary

This feasibility study identified the level of inter-observer consistency in orthodontic treatment planning associated with different diagnostic information formats and an insight into patient perception associated with the use of teleorthodontics. The data could be used for a larger scale investigation to be carried out to determine the efficacy of teleorthodontics.

CONCLUSION

6.1 First Aim

One observer showed consistently good and another had consistently moderate levels of intra-observer reproducibility of treatment plans when using clinical, hard copy and digital diagnostic information. However, when comparing treatment plans developed clinically with those developed from digital records, intra-observer reproducibility dropped markedly for the two other observers from good to fair and fair to poor respectively.

The null hypothesis that there is no difference in intra-observer treatment planning decisions, regardless of the diagnostic information used, is rejected in the case of two observers, but supported by two others.

6.2 Second Aim

Inter-observer reproducibility of treatment planning decisions reduced from moderate when using hard copy records to fair when using digital records.

The null hypothesis, that there is no difference in inter-observer treatment planning decisions regardless of format of diagnostic information, is therefore rejected.

6.3 Third Aim

The conventional face-to-face orthodontic consultation was found to be very satisfactory for two thirds of subjects. No subjects described this consultation as unsatisfactory.

There was an inadequate number of subjects recruited from remote and rural areas to accept or reject the null hypothesis that there is no difference in satisfaction with the conventional consultation system between urban and remote and rural patients.

6.4 Fourth Aim

Only two subjects recruited to the study lived in remote and rural areas. They reported that neither would mind if they were referred using teleorthodontics as both thought this technology would make it easier for an orthodontic consultation to be provided. Both felt this had the potential to save them time and money, with one feeling it would result in less inconvenience.

There was an inadequate number of remote and rural subjects recruited to accept or reject whether there was a difference in the perceived benefits in the use of digital records for remote referrals between urban and remote and rural patients.

FUTURE WORK

It is hoped that this feasibility study can be used for the development of an adequately powered, prospective, observational, cross-sectional investigation to assess treatment planning reproducibility comparing teleorthodontic and conventional methods.

It would beneficial for this to be a multi-centre investigation, allowing subjects to be recruited from rural as well as urban areas of the country. This may require providing GDPs or community dental centres in rural areas with equipment to enable acceptable gathering of digital information in order that the teleorthodontic referral and treatment planning process can be replicated.

A more user-friendly means of accessing and manipulating the digital records would be desirable as well as provision of a tutorial to the observers in the use of this format would hopefully limit systematic error as well as randomising the order of the provision of the diagnostic information.

With an increased sample size, treatment plan options could also be more detailed, enabling investigation of treatment planning reproducibility more precisely.

With more time, all observers would have an opportunity to carry out treatment planning using clinical information for ever subject, as well as hard copy and digital records. This would allow investigation of inter-observer reproducibility for clinical exams to be carried out.

It would be desirable to spend additional time in producing a valid questionnaire for assessing urban and rural subjects' opinions on the use of teleorthodontics. It would also be worthwhile ensuring that the language in the questionnaire is appropriate for the subjects recruited.

APPENDICES

Appendix 1

Digital Orthodontic Treatment Planning: Does it Work?

We'd like to invite you to take part in some research. Please read this leaflet and talk about it with people at home. If you have any questions about it, ask one of the orthodontists

What is the research about?

We are trying to find if orthodontists can plan your brace treatment without you coming to the Dental Hospital. Only digital information would be used to plan your brace treatment

What will you have to do?

- Come to an appointment at the Dental Hospital as normal. At this, 2 orthodontists will decide if you need braces and a mould of your teeth will be taken, some photos, 3D pictures of your face and maybe some X-rays
- Fill in a questionnaire at a follow up appointment

How long will it take?

About half an hour longer than usual

Can everyone take part in the study?

No, if you're under 12 or still have lots of baby teeth you won't take part

Do I have to take part?

You don't have to take part in the research and you can stop at any time without giving a reason. This will not affect your chances of getting braces or your treatment.

If you are worried about taking part in the research or you want to leave, speak to one of the orthodontists who will answer any questions you have or arrange for you to leave the trial

Thanks for reading this leaflet and thinking about taking part in the research.

Appendix 2

Digital Orthodontic Treatment Planning: Does it Work?

My name is Craig Dunbar and I am doing an MSc at Dundee University. I am required to undertake a project as part of my course and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.

How are Orthodontic treatment decisions normally made?

Patients are normally sent to an orthodontist if their dentist thinks they need treatment. They see the orthodontist who carries out an exam then takes records which include:

- impressions so that moulds of teeth can be kept,
- photographs of teeth and face
- X-rays to look at the health of the teeth and how jaws come together

When all this information has been gathered together the orthodontist can plan how to carry out treatment to give the best result.

How could digital records be used?

The above hard copy records could be taken by your dentist who could then send them digitally to the orthodontist. The orthodontist could then look at this information and decide whether or not you need treatment and draw up a plan. This could save you the hassle of having to come to the first few appointments. But, we would need to make sure that the decisions made using the digital records are right.

How are we going to test if digital planning works?

There is no set way for dentists to make digital records so this is what we'll do:

1. You'll come to a clinic for new patients where orthodontists will carry out an exam and come up with a plan on how to do your treatment.
2. Hard copy records will be taken and these will be used by the orthodontists to make another plan at least a month after the first exam
3. Digital versions of the hard copy records will be used for further planning by the orthodontists after another month

At the end there will be 3 sets of plans for you from each orthodontist. We will then be able to compare these and find how accurate the plan is that was made using only the electronic information.

What will you have to do?

- Attend the clinic for new patients as you would normally. This involves an exam from 2 orthodontists and one set of records being taken (moulds, photographs, X-rays, 3D picture of your face)
- Fill in a questionnaire to find what you thought of the normal way you're sent to see the orthodontist and whether you think using digital information would have any benefits

How long will the study take?

Agreeing to take part in the research, extra exams and filling in the questionnaire will mean that the appointment will take around 30 minutes longer than usual. There will be no further impact on your treatment after the first appointment.

Can everyone take part in the study?

No, you will be excluded from the study if any of the following statements apply:
You have previously had orthodontic treatment
The original paperwork from your dentist is not in your notes
You have a cleft lip/palate
You are younger than 12 or still have adult teeth due to come through
If you can't understand the written and spoken explanations of the study

When should you make your decision about taking part in the study?

It would be good if you could read the information in the leaflet and understand what is involved in the study before you attend your appointment. This would mean that if you are willing to take part, your appointment would be quicker as less time would be needed to explain the study before you could give informed consent.

What if something goes wrong?

If you have a complaint about taking part in the study you should first talk to a researcher involved in your care. You can ask to speak to a senior member of the research team or the Complaints Officer for NHS Tayside.

In the event that something goes wrong and you are harmed during the study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Dundee or NHS Tayside but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Complaints and Claims Manager

Complaints and Advice Team
Level 7, Ninewells Hospital
Dundee DD1 9SY
Freephone: 0800 027 5507
Email: nhstaysidecomplaints@thb.scot.nhs.uk

What if you want to leave the study?

You can refuse to take part in the study or withdraw at any stage without giving a reason. This will not affect your treatment or relationship with staff treating you. Any previous information provided by you before withdrawing may still be used in the study but no further information will be gathered.

Will you receive any payment for taking part in the study?

No.

Will the information we gather from you be confidential?

The Tayside Ethics Committee, which has examined the plan for this research and has raised no objections.
Your clinical notes and records will be kept confidential as set out by Dundee Dental Hospital and NHS Tayside.
When completing your questionnaire, you will be given a unique identification number which will allow your answers to remain anonymous.

It is hoped that the results of the study may be presented at conferences or published in journals. If this happens some digital records may be used to illustrate presentations. If this happens, we will look to get consent from you to make sure that this is OK.

If you have any questions on the day of your appointment about the study, Dr Craig Dunbar, Dr Grant McIntyre and Professor David Bearn will all be present for these to be answered.

Thank you for reading this information and considering taking part in the study.

If you have any immediate questions please contact:

Orthodontic reception: 01382 635964
Craig Dunbar: craig.dunbar@nhs.net
Grant McIntyre: grant.mcintyre@nhs.net
David Bearn: d.bearn@dundee.ac.uk

Appendix 3

A Study of the Use of Digital Records for Orthodontic Treatment Planning
Patient Information

My name is Craig Dunbar and I am undertaking an MSc at Dundee University. I am required to undertake a project as part of my course and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.

How are Orthodontic treatment decisions normally made?

Patients are normally sent to an orthodontist if their dentist thinks they would benefit from treatment. They see the orthodontist who carries out a clinical assessment then takes records which include:

- impressions so that moulds of teeth can be kept,
- photographs of teeth and face
- X-rays to look at the health of the teeth and how jaws come together

Once all this information has been gathered together the orthodontist can plan how to carry out treatment to give the best result.

How could electronic records be used?

The above hard copy records could be taken by your dentist who could then send them electronically to the orthodontist. The orthodontist could then look at this information and decide if you would benefit from treatment and draw up a plan. This could save you the hassle of having to attend the first few appointments. However, we would need to make sure that the decisions being made using the electronic information are accurate.

How are we going to test if treatment planning is accurate using electronic information?

There is no set way for dentists to make electronic records at this stage so the following method will be used:

1. You will attend a new patient assessment clinic where orthodontists will carry out an examination and draw up an initial plan
2. Hard copy records will be taken and these will be used by the orthodontists to make another plan at least a month after the initial assessment
3. Electronic versions of the hard copy records will be used for further treatment planning by the orthodontists after another month

At the end there will be 3 sets of plans for you from each orthodontist. We will then be able to compare these and find how accurate the plan is that was made using only the electronic information.

What will you have to do?

- Attend one new patient clinic as normal. This would involve an examination from 2 orthodontists and the taking of one set of records (impressions, photographs, X-rays, 3D face scan)
- Complete a questionnaire to assess what you thought of the normal referral process and whether you think using electronic information would have any benefits

How long will the study take?

Giving consent, extra examinations and filling in the questionnaire will mean that the appointment will take around 30 minutes longer than usual. There will be no further impact on your treatment after the first appointment.

Can everyone take part in the study?

No, you will be excluded from the study if any of the following statements apply:
You have previously undergone orthodontic treatment
You do not have an original referral letter in your notes
You have a cleft lip/palate
You are younger than 12 years of age or still have adult teeth due to come through
If you are unable to understand the written and verbal explanations of the study in order for informed consent to be given

When should you make your decision about taking part in the study?

It would be good if you could read the information in the leaflet and understand what is involved in the study before you attend your appointment. This would mean that if you are willing to take part, your appointment would be quicker as less time would be needed to explain the study before you could give informed consent.

What if something goes wrong?

If you have a complaint about your participation in the study you should first talk to a researcher involved in your care. You can ask to speak to a senior member of the research team or the Complaints Officer for NHS Tayside.

In the event that something goes wrong and you are harmed during the study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Dundee or NHS Tayside but you may have to pay your legal

costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Complaints and Claims Manager
Complaints and Advice Team
Level 7, Ninewells Hospital
Dundee DD1 9SY
Freephone: 0800 027 5507
Email: nhstaysidecomplaints@thb.scot.nhs.uk

What if you want to leave the study?

You can refuse to take part in the study or withdraw at any stage without giving a reason. This will not affect your treatment or relationship with staff providing your care. Any previous information provided by you before withdrawal may still be used in the study but no further information will be gathered.

Will you receive any payment for taking part in the study?

There will be no payment for taking part in the study.

Will the information we gather from you be confidential?

The Tayside Committee on Medical Research Ethics, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. Your clinical notes and records will be subject to standard patient confidentiality adhered to in Dundee Dental Hospital and NHS Tayside.
For completion of your questionnaire you will be given a unique identification number which will allow your responses to remain anonymous.

It is hoped that the results of the study may be presented at conferences or published in journals. If this is the case some electronic records may be used for illustrative purposes. If this is the case further consent will be sought from you in order for this to occur.

If you have any queries on the day of your appointment about the study, Dr Craig Dunbar, Dr Grant McIntyre and Professor David Bearn will all be present in order for these to be answered.

Thank you for reading this information and considering taking part in the study.

If you have any immediate questions please contact:

Orthodontic reception: 01382 635964
Craig Dunbar: craig.dunbar@nhs.net
Grant McIntyre: grant.mcintyre@nhs.net
David Bearn: d.bearn@dundee.ac.uk

Appendix 4

QUESTIONNAIRE:

Cover letter:

Your dentist recently asked for you to be seen to decide if you might need Orthodontic treatment. This was done using the usual method of your dentist sending a referral to an Orthodontist who then asked you to attend an appointment at a hospital for a consultation to be carried out.

There is a different way to refer you where records (moulds of teeth, photos, X-rays etc.) are taken at your local high street dentists' and these are then sent electronically to the Orthodontist. They are then able to look at the records and give an opinion on whether Orthodontic treatment is required without the need for you to attend the first appointment.

The aim of this questionnaire is to gauge how happy you are with the usual referral system and also those of any accompanying adults if present.

Please answer these questions and ask for advice from the adult who came with you if needed. If you don't know exact answers, guesses are acceptable.

Questionnaire: Subject no. _____

Patient

- Age of patient? ☐
- Postcode: _____
- Male or female? Male___
  Female___
- Who's idea was it to see the Orthodontist? Dentist___
  Parent___
  Your idea___
  Someone else's___ Who?_____
  Can't remember____

Initial appointment at Orthodontist

- How easy was it for you to get an appointment with the Orthodontist?
  Very easy___ Easy___ OK___ Difficult___ Very difficult___
- How long was it from your referral by your dentist to your Orthodontic appointment?
  ___weeks

- How far is it from your home to the Orthodontic department?
  ___miles

- Did you receive enough information about Orthodontic treatment at this appointment?
  No___
  Yes___

- How was Orthodontic information given to you?
  Leaflet _____
  Video _____
  The Orthodontist talked to me _____
  The Orthodontist showed me pictures _____
  Someone else showed me pictures _____
  I didn't get any information _____
  Can't remember _____

- Were all of your questions answered about Orthodontic treatment at the consultation?
  Yes fully___ Partially___ Not at all___

Following the Orthodontic Appointment

- "I felt that there was enough attention paid to my case by the Orthodontist"
  Yes fully___ Partially___ Not at all___

- "I agreed with the Orthodontist's findings"
  Yes fully___ Partially___ Not at all___

- "Following the Orthodontic appointment I was advised to have Orthodontic treatment"
  No___ Yes___

- "I am going to have Orthodontic treatment"
  No___ Yes___

Opinion of face-to-face consultation

- Do you feel that face-to-face communication is important in Orthodontic treatment?
  Not important___ Some importance___ Extremely important___
- Did you feel the face-to-face consultation provided a good quality of care?

Yes fully___ Partially___ Not at all___

- Would you have preferred your referral and Orthodontic consultation to have been carried out electronically without a face-to-face visit?
  No___ Don't mind___ Yes___

- Compared to a face-to-face consultation, do you think having an electronic referral would have saved you:
  Time? No___
  Yes___
  Money? No___
  Yes___
  Hassle? No___
  Yes___

- Do you think that an electronic referral would have made it easier for you to receive an Orthodontic opinion?
  Yes fully___ Partially___ Not at all___

- What are your general feelings about face-to-face Orthodontic consultations?
  Very satisfied _____
  Partially satisfied _____
  OK _____
  Unsatisfied _____
  Very unsatisfied _____

Appendix 5

Centre Number: :DDH

Patient Identification Number for this trial:

INFORMED CONSENT FORM

Title of Project: A Study of the Use of Digital Records for Orthodontic Treatment Planning

Name of Researcher: Dr Craig Dunbar

		Please initial box
1	I confirm that I have read and understand the information sheet dated 05/03/2012 (version 1.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from NHS Tayside, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4	I understand that the results/findings of the research may be published, on the condition that patient confidentiality is maintained.	☐
5	I agree to my General Dental Practitioner being informed of my participation in the study.	☐
6	I agree to take part in the above study.	☐

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of Person providing consent (if different from patient)	Signature	Date
_____	_____	_____
Researcher	Signature	Date

1 for patient; 1 for researcher; 1 to be kept with hospital notes

Appendix 6

Centre Number::DDH
Patient Identification Number for this trial:

Title of Project: Digital Orthodontic Treatment Planning: Does it Work?

Name of Researcher: Craig Dunbar

Please sign the form below if:

- You have read and understood the leaflet 'Digital Orthodontic Treatment Planning: Does it Work?'
- You have had a chance to talk to people at home whether to take part in the research
- You have had all questions about the research answered
- You are happy to take part in the research

_____	_____	
Name of Patient	Signature	Date
_____	_____	
Researcher	Signature	Date

1 for patient; 1 for researcher; 1 to be kept with hospital notes

Appendix 7

Specialist Responses to Percentage Change in Treatment that would be Clinically Significant

Treatment	Growth Modification	Orthodontics	Surgery
Median	**5**	**10**	**3**

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